

Supplementary Materials

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Supplement A

Figure s1. PRISMA Flow Diagram

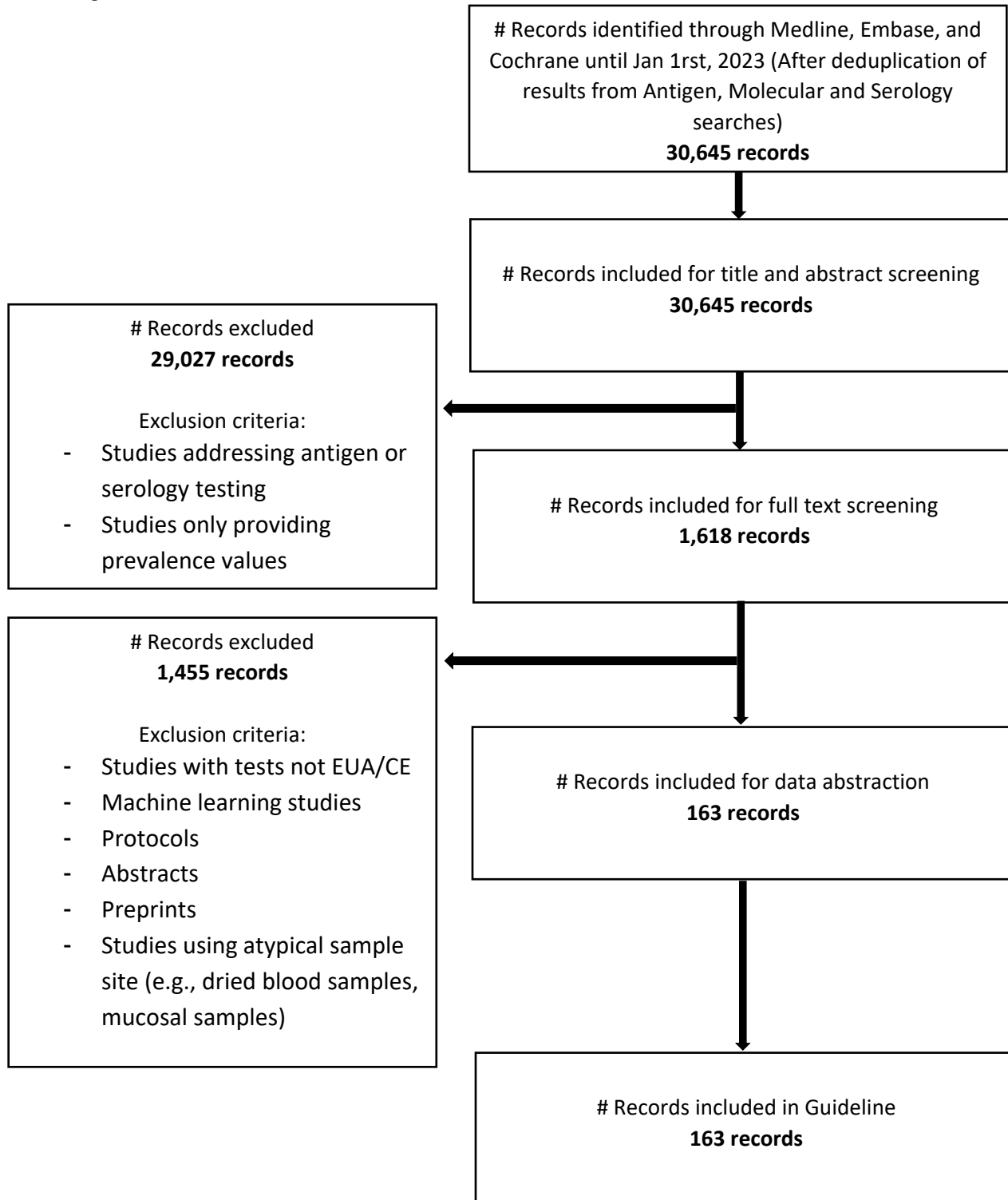


Table s1. PICO questions Identified by the Panel through the two guideline versions

Questions	Initial guideline (Sep 12, 2020)	Current Update
• Should serology testing vs. no testing be performed to detect active COVID-19 infection in symptomatic patients in the first two weeks after symptom onset?	✓	✓
• Should NAAT alone vs. NAAT plus serology (when initial NAAT is negative) be used to diagnose COVID-19 in symptomatic patients?	✓	✓
• Should serology testing vs. no testing be performed to detect COVID-19 infection in children suspected to have multisystem inflammatory syndrome (MISC)?	✓	✓
• Should IgM vs. IgG vs. IgM/IgG vs. Total Antibodies be used for SARS-CoV-2 antibody testing?	✓	✓
• Should rapid serology (capillary blood) vs. standard serology (venous blood) be used to detect SARS-CoV-2 antibodies?	✓	
• Should anti-spike vs anti-nucleocapsid antibodies be used for SARS-CoV-2 antibody testing?		✓
• Should serology testing vs not be performed in individuals with prior COVID-19 infection to improve patient important outcomes?		✓
• Should serology testing vs not be performed in vaccinated individuals to improve patient important outcomes?		✓

Table s2. Search Strategies

Antigen Search Strategy

PUBMED (Antigen) SEARCH DATE: up till 01/01/2023	
Set #	Search Strategy
1	("COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh])
2	("2019 novel*" [tiab] OR "2019-ncov" [tiab] OR 2019ncov [tiab] OR covid19 [tiab] OR covid2019 [tiab] OR "covid 2019" [tiab] OR "covid-19" [tiab] OR "hcov-19" [tiab] OR hcov19 [tiab] OR "n-cov" [tiab] OR "ncov-2019" [tiab] OR ncov [tiab] OR ncov2019 [tiab] OR "novel betacoronavirus" [tiab] OR "Novel Coronavirus" [tiab] OR "novel CoV" [tiab] OR "sars-cov19" [tiab] OR "sars-cov-19" [tiab] OR sarscov19 [tiab] OR "sarscov2" [tiab] OR "sarscov-2" [tiab] OR "sars-cov2" [tiab] OR "sars-cov-2" [tiab])
3	((epidem* [tiab] OR outbreak* [tiab] OR pandem* [tiab] OR wildlife* [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab]))
4	((respiratory [tiab] AND (condition* [tiab] OR disease* [tiab] OR illness* [tiab] OR symptom* [tiab])) OR "food market*" [tiab] OR "seafood market*" [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab] OR hubei* [tiab] OR wuhan* [tiab]))
5	OR/1-4
6	"Antigens, Viral"[Mesh]
7	antigen [tiab]
8	OR/6-7
9	"COVID-19 Testing"[Mesh] OR "Delayed Diagnosis"[Mesh] OR "Diagnosis"[Mesh:NoExp] OR "Diagnosis, Differential"[Mesh] OR "Diagnostic Techniques and Procedures"[Mesh] OR "Early Diagnosis"[Mesh]
10	"diagnosis"[Subheading]
11	case* [tiab] OR "case finding" [tiab] OR casefinding [tiab] OR detect* [tiab] OR diagnos* [tiab] OR screen* [tiab] OR test* [tiab]
12	OR/9-11
13	5 AND 8 AND 12
14	English [Language]
15	13 AND 14
16	animals [Mesh] NOT humans [Mesh]
17	15 NOT 16
18	"2021/02/22"[PDAT] : "3000/12/31"[PDAT]
19	17 AND 18

20	("Academic Dissertation"[Publication Type] OR "address"[Publication Type] OR "Anecdotes"[Publication Type] OR "Animation"[Publication Type] OR "autobiography"[Publication Type] OR "bibliography"[Publication Type] OR "biography"[Publication Type] OR "Book Illustrations"[Publication Type] OR "Book Review"[Publication Type] OR "Bookplate"[Publication Type] OR "Cartoon"[Publication Type] OR "Case Reports"[Publication Type] OR "Catalog"[Publication Type] OR "Chart"[Publication Type] OR "Comment"[Publication Type] OR "congress"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "dictionary"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "Expression of Concern"[Publication Type] OR "Guideline"[Publication Type] OR "Handbook"[Publication Type] OR "interactive tutorial"[Publication Type] OR "interview"[Publication Type] OR "Juvenile Literature"[Publication Type] OR "lecture"[Publication Type] OR "legal case"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "Meeting Abstract"[Publication Type] OR "Meta-Analysis"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "overall"[Publication Type] OR "patient education handout"[Publication Type] OR "periodical index"[Publication Type] OR "personal narrative"[Publication Type] OR "portrait"[Publication Type] OR "Review"[Publication Type] OR "Scientific Integrity Review"[Publication Type] OR "Systematic Review"[Publication Type] OR "Unpublished Work"[Publication Type] OR "hascommenton"[All Fields] OR "Cartoons as Topic"[Mesh] OR "Meta-Analysis as Topic"[Mesh] OR "Review Literature as Topic"[Mesh] OR "Systematic Reviews as Topic"[Mesh] OR "case report*"[tiab] OR "integrative research review*"[tiab] OR "integrative review*"[tiab] OR "literature review"[tiab] OR meta-analys*[tiab] OR "meta analys*"[tiab] OR metaanalys*[tiab] OR "narrative review"[tiab] OR "research integration"[tiab] OR "scoping review"[tiab] OR ((methodologic*[tiab] OR quantitative*[tiab] OR systematic*[tiab]) AND (overview*[tiab] OR review*[tiab] OR synthesis*[tiab])))
21	19 NOT 20

EMBASE (Antigen) SEARCH DATE: up till 01/01/2023	
Set #	Search Strategy
1	('coronavirus disease 2019'/exp OR 'Severe acute respiratory syndrome coronavirus 2'/exp)

2	((('2019 novel*' OR '2019-ncov' OR 2019ncov OR corvid19 OR 'corvid-19' OR cov19 OR covid19 OR covid2019 OR 'covid 2019' OR 'covid-19' OR 'hcov-19' OR hcov19 OR ncorona* OR ncorono* OR 'n-cov' OR 'ncov-2019' OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR 'novel betacoronavirus' OR 'Novel Coronavirus' OR 'novel CoV' OR 'sarscov-19' OR 'sars-cov19' OR 'sars-cov-19' OR sarscov19 OR 'sarscov2' OR 'sarscov-2' OR 'sars-cov2' OR 'sars-cov-2' OR 'wn-cov' OR wncov):ti,ab)
3	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
4	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR 'food market*' OR 'seafood market*') AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
6	('virus antigen'/exp)
7	antigen:ti,ab
8	OR/6-7
9	('delayed diagnosis'/exp OR 'diagnosis'/de OR 'diagnostic procedure'/de OR 'differential diagnosis'/exp OR 'early diagnosis'/exp OR 'examination'/exp OR 'laboratory diagnosis'/exp OR 'physical examination'/exp OR 'qualitative diagnosis'/exp OR 'quantitative diagnosis'/exp OR 'screening'/exp OR 'symptom assessment'/exp OR 'virus diagnosis'/exp)
10	(case* OR 'case finding' OR casefinding OR detect* OR diagnos* OR screen* OR test*):ti,ab
11	OR/9-10
12	5 AND 8 AND 11
13	[english]/lim
14	12 AND 13
15	[animals]/lim NOT [humans]/lim
16	14 NOT 15
17	('abstract report'/exp OR 'animal experiment'/exp OR 'book'/exp OR 'case finding'/exp OR 'case report'/exp OR 'case study'/exp OR 'conference paper'/exp OR 'editorial'/exp OR 'feasibility study'/exp OR 'in vitro study'/exp OR 'letter'/exp OR 'meta analysis'/exp OR 'meta analysis topic'/exp OR 'meta analysis (topic)'/exp OR 'note'/exp OR 'practice guideline'/exp OR 'review'/exp OR 'systematic review'/exp OR 'systematic review topic'/exp OR 'systematic review (topic)'/exp OR 'veterinary clinical trial'/exp OR 'veterinary study'/exp OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim OR [short survey]/lim OR meta*analys*:ti,ab OR (integrative NEAR/5 research NEAR/5 review*):ti,ab OR (methodologic* NEAR/5 overview*):ti,ab OR (methodologic* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 overview*):ti,ab OR (quantitativ* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 synthesi*):ti,ab OR (research NEAR/5

	integration):ti,ab OR (systematic* NEAR/5 overview*):ti,ab OR (systematic* NEAR/5 review*):ti,ab)
18	16 NOT 17
19	(([01-08-2022]/sd NOT [01-09-2022]/sd) AND [2022-2022]/py)
20	18 AND 19

Cochrane SEARCH DATE: 9/6/2022	
Set #	Search Strategy
1	(MeSH descriptor: [COVID-19] explode all trees OR MeSH descriptor: [SARS-CoV-2] explode all trees)
2	((("2019 novel" OR "2019-ncov" OR 2019ncov OR corvid19 OR "corvid-19" OR cov19 OR covid19 OR covid2019 OR "covid 2019" OR "covid-19" OR "hcov-19" OR hcov19 OR ncorona* OR ncorono* OR "n-cov" OR "ncov-2019" OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR "novel betacoronavirus" OR "Novel Coronavirus" OR "novel CoV" OR "sarscov-19" OR "sars-cov19" OR "sars-cov-19" OR sarscov19 OR "sarscov2" OR "sarscov-2" OR "sars-cov2" OR "sars-cov-2" OR "wn-cov" OR wncov):ti,ab)
3	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
4	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR "food market*" OR "seafood market*") AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
6	"Antigens, Viral"[Mesh]
7	antigen:ti,ab
8	OR/6-7
9	MeSH descriptor: [Delayed Diagnosis] explode all trees
10	MeSH descriptor: [Diagnosis] this term only
11	MeSH descriptor: [Diagnosis, Differential] explode all trees
12	MeSH descriptor: [Diagnostic Techniques and Procedures] explode all trees
13	MeSH descriptor: [Early Diagnosis] explode all trees
14	Any MeSH descriptor in all MeSH products and with qualifier(s): [diagnosis - DI]
15	case* OR "case finding" OR casefinding OR detect* OR diagnos* OR screen* OR test*
16	OR/9-15
17	5 AND 8 AND 16
18	August 1-31, 2022
19	17 AND 18

Molecular Search Strategy

PUBMED (Molecular) SEARCH DATE: up till 01/01/2023	
Set #	Search Strategy
1	("COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh])
2	("2019 novel*" [tiab] OR "2019-ncov" [tiab] OR 2019ncov [tiab] OR covid19 [tiab] OR covid2019 [tiab] OR "covid 2019" [tiab] OR "covid-19" [tiab] OR "hcov-19" [tiab] OR hcov19 [tiab] OR "n-cov" [tiab] OR "ncov-2019" [tiab] OR ncov [tiab] OR ncov2019 [tiab] OR "novel betacoronavirus" [tiab] OR "Novel Coronavirus" [tiab] OR "novel CoV" [tiab] OR "sars-cov19" [tiab] OR "sars-cov-19" [tiab] OR sarscov19 [tiab] OR "sarscov2" [tiab] OR "sarscov-2" [tiab] OR "sars-cov2" [tiab] OR "sars-cov-2" [tiab])
3	((epidem* [tiab] OR outbreak* [tiab] OR pandem* [tiab] OR wildlife* [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab]))
4	((((respiratory [tiab] AND (condition* [tiab] OR disease* [tiab] OR illness* [tiab] OR symptom* [tiab])) OR "food market*" [tiab] OR "seafood market*" [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab] OR hubei* [tiab] OR wuhan* [tiab]))
5	OR/1-4
6	"Molecular Diagnostic Techniques"[Mesh] OR "Polymerase Chain Reaction"[Mesh]
7	"molecular diagnosis" [tiab] OR "molecular diagnostics" [tiab] OR "Molecular Diagnostic Technique" [tiab] OR "Molecular Diagnostic Testing" [tiab] OR "Molecular Testing" [tiab] OR "PCR Test" [tiab] OR "PCR Testing" [tiab] OR "Polymerase reaction chain" [tiab]
8	OR/6-7
9	"COVID-19 Testing"[Mesh] OR "Delayed Diagnosis"[Mesh] OR "Diagnosis"[Mesh:NoExp] OR "Diagnosis, Differential"[Mesh] OR "Diagnostic Techniques and Procedures"[Mesh] OR "Early Diagnosis"[Mesh]
10	"diagnosis"[Subheading]
11	case* [tiab] OR "case finding" [tiab] OR casefinding [tiab] OR detect* [tiab] OR diagnos* [tiab] OR screen* [tiab] OR test* [tiab]
12	OR/9-11
13	6 AND 9 AND 13
14	English[Language]
15	13 AND 14
16	animals[Mesh] NOT humans[Mesh]
17	15 NOT 16
18	"2022/08/01"[PDAT] : "2022/08/31"[PDAT]
19	17 AND 18

20	("Academic Dissertation"[Publication Type] OR "address"[Publication Type] OR "Anecdotes"[Publication Type] OR "Animation"[Publication Type] OR "autobiography"[Publication Type] OR "bibliography"[Publication Type] OR "biography"[Publication Type] OR "Book Illustrations"[Publication Type] OR "Book Review"[Publication Type] OR "Bookplate"[Publication Type] OR "Cartoon"[Publication Type] OR "Case Reports"[Publication Type] OR "Catalog"[Publication Type] OR "Chart"[Publication Type] OR "Comment"[Publication Type] OR "congress"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "dictionary"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "Expression of Concern"[Publication Type] OR "Guideline"[Publication Type] OR "Handbook"[Publication Type] OR "interactive tutorial"[Publication Type] OR "interview"[Publication Type] OR "Juvenile Literature"[Publication Type] OR "lecture"[Publication Type] OR "legal case"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "Meeting Abstract"[Publication Type] OR "Meta-Analysis"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "overall"[Publication Type] OR "patient education handout"[Publication Type] OR "periodical index"[Publication Type] OR "personal narrative"[Publication Type] OR "portrait"[Publication Type] OR "Review"[Publication Type] OR "Scientific Integrity Review"[Publication Type] OR "Systematic Review"[Publication Type] OR "Unpublished Work"[Publication Type] OR "hascommenton"[All Fields] OR "Cartoons as Topic"[Mesh] OR "Meta-Analysis as Topic"[Mesh] OR "Review Literature as Topic"[Mesh] OR "Systematic Reviews as Topic"[Mesh] OR "case report*"[tiab] OR "integrative research review*"[tiab] OR "integrative review*"[tiab] OR "literature review"[tiab] OR meta-analys*[tiab] OR "meta analys*"[tiab] OR metaanalys*[tiab] OR "narrative review"[tiab] OR "research integration"[tiab] OR "scoping review"[tiab] OR ((methodologic*[tiab] OR quantitative*[tiab] OR systematic*[tiab]) AND (overview*[tiab] OR review*[tiab] OR synthesis*[tiab])))
21	19 NOT 20

EMBASE (Molecular)

SEARCH DATE: up till 01/01/2023

Set #	Search Strategy
1	('coronavirus disease 2019'/exp OR 'Severe acute respiratory syndrome coronavirus 2'/exp)

IDSA Guidelines on the Diagnosis of COVID-19: Serologic Testing
Supplementary Materials

	((('2019 novel*' OR '2019-ncov' OR 2019ncov OR corvid19 OR 'corvid-19' OR cov19 OR covid19 OR covid2019 OR 'covid 2019' OR 'covid-19' OR 'hcov-19' OR hcov19 OR ncorona* OR ncorono* OR 'n-cov' OR 'ncov-2019' OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR 'novel betacoronavirus' OR 'Novel Coronavirus' OR 'novel CoV' OR 'sarscov-19' OR 'sars-cov19' OR 'sars-cov-19' OR sarscov19 OR 'sarscov2' OR 'sarscov-2' OR 'sars-2cov2' OR 'sars-cov-2' OR 'wn-cov' OR wncov):ti,ab)
	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR 'food market*' OR 'seafood market*') AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
	molecular diagnosis'/exp OR 'molecular diagnostics'/exp OR 'molecular testing'/exp OR 'polymerase chain reaction'/exp OR 'SARS coronavirus 2 nucleic acid test kit'/exp
	((("molecular diagnosis" OR "molecular diagnostics" OR "Molecular Diagnostic Technique" OR "Molecular Diagnostic Testing" OR "Molecular Testing" OR "PCR Test" OR "PCR Testing" OR "Polymerase reaction chain"):ti,ab)
8	OR/6-7
	('delayed diagnosis'/exp OR 'diagnosis'/de OR 'diagnostic procedure'/de OR 'differential diagnosis'/exp OR 'early diagnosis'/exp OR 'examination'/exp OR 'laboratory diagnosis'/exp OR 'physical examination'/exp OR 'qualitative diagnosis'/exp OR 'quantitative diagnosis'/exp OR 'screening'/exp OR 'symptom assessment'/exp OR 'virus diagnosis'/exp)
10	(case* OR 'case finding' OR casefinding OR detect* OR diagnos* OR screen* OR test*):ti,ab
11	OR/9-10
12	5 AND 8 AND 11
13	[english]/lim
14	12 AND 13
15	[animals]/lim NOT [humans]/lim
16	14 NOT 15

	('abstract report'/exp OR 'animal experiment'/exp OR 'book'/exp OR 'case finding'/exp OR 'case report'/exp OR 'case study'/exp OR 'conference paper'/exp OR 'editorial'/exp OR 'feasibility study'/exp OR 'in vitro study'/exp OR 'letter'/exp OR 'meta analysis'/exp OR 'meta analysis topic'/exp OR 'meta analysis (topic)'/exp OR 'note'/exp OR 'practice guideline'/exp OR 'review'/exp OR 'systematic review'/exp OR 'systematic review topic'/exp OR 'systematic review (topic)'/exp OR 'veterinary clinical trial'/exp OR 'veterinary study'/exp OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim OR [short survey]/lim OR meta*analys*:ti,ab OR (integrative NEAR/5 research NEAR/5 review*):ti,ab OR (methodologic* NEAR/5 overview*):ti,ab OR (methodologic* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 overview*):ti,ab OR (quantitativ* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 syntheses*):ti,ab OR (research NEAR/5 integration):ti,ab OR (systematic* NEAR/5 overview*):ti,ab OR (systematic* NEAR/5 review*):ti,ab)
18	16 NOT 17
19	((([01-08-2022]/sd NOT [01-09-2022]/sd) AND [2022-2022]/py)
20	18 AND 19

Cochrane (Molecular) SEARCH DATE: up till 01/01/2023	
Set #	Search Strategy
1	(MeSH descriptor: [COVID-19] explode all trees OR MeSH descriptor: [SARS-CoV-2] explode all trees)
2	((("2019 novel" OR "2019-ncov" OR 2019ncov OR corvid19 OR "corvid-19" OR cov19 OR covid19 OR covid2019 OR "covid 2019" OR "covid-19" OR "hcov-19" OR hcov19 OR ncorona* OR ncorono* OR "n-cov" OR "ncov-2019" OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR "novel betacoronavirus" OR "Novel Coronavirus" OR "novel CoV" OR "sarscov-19" OR "sars-cov19" OR "sars-cov-19" OR sarscov19 OR "sarscov2" OR "sarscov-2" OR "sars-cov2" OR "sars-cov-2" OR "wn-cov" OR wncov):ti,ab)
3	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
4	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR "food market*" OR "seafood market*") AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
6	MeSH descriptor: [Molecular Diagnostic Techniques] explode all trees OR MeSH descriptor: [Polymerase Chain Reaction] explode all trees
7	("molecular diagnosis" OR "molecular diagnostics" OR "Molecular Diagnostic Technique" OR "Molecular Diagnostic Testing" OR "Molecular Testing" OR "PCR Test" OR "PCR Testing" OR "Polymerase reaction chain"):ti,ab

8	OR/6-7
9	MeSH descriptor: [Delayed Diagnosis] explode all trees
10	MeSH descriptor: [Diagnosis] this term only
11	MeSH descriptor: [Diagnosis, Differential] explode all trees
12	MeSH descriptor: [Diagnostic Techniques and Procedures] explode all trees
13	MeSH descriptor: [Early Diagnosis] explode all trees
14	Any MeSH descriptor in all MeSH products and with qualifier(s): [diagnosis - DI]
15	case* OR "case finding" OR casefinding OR detect* OR diagnos* OR screen* OR test*
16	OR/9-15
17	5 AND 8 AND 16
18	August 1-31, 2022
19	17 AND 18

Serology Search Strategy

PUBMED (Serology) SEARCH DATE: up till 01/01/2023	
Set #	Search Strategy
1	("COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh])
2	("2019 novel*" [tiab] OR "2019-ncov" [tiab] OR 2019ncov [tiab] OR covid19 [tiab] OR covid2019 [tiab] OR "covid 2019" [tiab] OR "covid-19" [tiab] OR "hcov-19" [tiab] OR hcov19 [tiab] OR "n-cov" [tiab] OR "ncov-2019" [tiab] OR ncov [tiab] OR ncov2019 [tiab] OR "novel betacoronavirus" [tiab] OR "Novel Coronavirus" [tiab] OR "novel CoV" [tiab] OR "sars-cov19" [tiab] OR "sars-cov-19" [tiab] OR sarscov19 [tiab] OR "sarscov2" [tiab] OR "sarscov-2" [tiab] OR "sars-cov2" [tiab] OR "sars-cov-2" [tiab])
3	((epidem* [tiab] OR outbreak* [tiab] OR pandem* [tiab] OR wildlife* [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab]))
4	((respiratory [tiab] AND (condition* [tiab] OR disease* [tiab] OR illness* [tiab] OR symptom* [tiab])) OR "food market*" [tiab] OR "seafood market*" [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab] OR hubei* [tiab] OR wuhan* [tiab]))
5	OR/1-4
6	"COVID-19 Serological Testing" [Mesh] OR "Immunoglobulin A" [Mesh] OR "Immunoglobulin G" [Mesh] OR "Immunoglobulin M" [Mesh] OR "Serologic Tests" [Mesh] OR "Serology" [Mesh]
7	"19S Gamma Globulin" [tiab] OR "7S Gamma Globulin" [tiab] OR Allerglobuline [tiab] OR IgA [tiab] OR IgG [tiab] OR IgM [tiab] OR Polyglobin [tiab] OR Serodiagnos* [tiab] OR Serologic* [tiab]
8	OR/6-7

9	"COVID-19 Testing"[Mesh] OR "Delayed Diagnosis"[Mesh] OR "Diagnosis"[Mesh:NoExp] OR "Diagnosis, Differential"[Mesh] OR "Diagnostic Techniques and Procedures"[Mesh] OR "Early Diagnosis"[Mesh]
10	"diagnosis"[Subheading]
11	case*[tiab] OR "case finding"[tiab] OR casefinding[tiab] OR detect*[tiab] OR diagnos*[tiab] OR screen*[tiab] OR test*[tiab]
12	OR/9-11
13	5 AND 8 AND 12
14	English[Language]
15	13 AND 14
16	animals[Mesh] NOT humans[Mesh]
17	15 NOT 16
18	"2022/08/01"[PDAT] : "2022/08/31"[PDAT]
19	17 AND 18
20	(("Academic Dissertation"[Publication Type] OR "address"[Publication Type] OR "Anecdotes"[Publication Type] OR "Animation"[Publication Type] OR "autobiography"[Publication Type] OR "bibliography"[Publication Type] OR "biography"[Publication Type] OR "Book Illustrations"[Publication Type] OR "Book Review"[Publication Type] OR "Bookplate"[Publication Type] OR "Cartoon"[Publication Type] OR "Case Reports"[Publication Type] OR "Catalog"[Publication Type] OR "Chart"[Publication Type] OR "Comment"[Publication Type] OR "congress"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "dictionary"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "Expression of Concern"[Publication Type] OR "Guideline"[Publication Type] OR "Handbook"[Publication Type] OR "interactive tutorial"[Publication Type] OR "interview"[Publication Type] OR "Juvenile Literature"[Publication Type] OR "lecture"[Publication Type] OR "legal case"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "Meeting Abstract"[Publication Type] OR "Meta-Analysis"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "overall"[Publication Type] OR "patient education handout"[Publication Type] OR "periodical index"[Publication Type] OR "personal narrative"[Publication Type] OR "portrait"[Publication Type] OR "Review"[Publication Type] OR "Scientific Integrity Review"[Publication Type] OR "Systematic Review"[Publication Type] OR "Unpublished Work"[Publication Type] OR "hascommenton"[All Fields] OR "Cartoons as Topic"[Mesh] OR "Meta-Analysis as Topic"[Mesh] OR "Review Literature as Topic"[Mesh] OR "Systematic Reviews as Topic"[Mesh] OR "case report*[tiab] OR "integrative research review*[tiab] OR "integrative review*[tiab] OR "literature review"[tiab] OR meta-analys*[tiab] OR "meta analys*[tiab] OR metaanalys*[tiab] OR "narrative review"[tiab] OR "research integration"[tiab] OR "scoping review"[tiab] OR ((methodologic*[tiab] OR quantitative*[tiab] OR systematic*[tiab]) AND (overview*[tiab] OR review*[tiab] OR synthesis*[tiab])))

21	19 NOR 20
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EMBASE (Serology) SEARCH DATE: 01/01/2023	
Set #	Search Strategy
1	('coronavirus disease 2019'/exp OR 'Severe acute respiratory syndrome coronavirus 2'/exp)
2	((('2019 novel*' OR '2019-ncov' OR 2019ncov OR corvid19 OR 'corvid-19' OR cov19 OR covid19 OR covid2019 OR 'covid 2019' OR 'covid-19' OR 'hcov-19' OR hcov19 OR ncorona* OR ncorono* OR 'n-cov' OR 'ncov-2019' OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR 'novel betacoronavirus' OR 'Novel Coronavirus' OR 'novel CoV' OR 'sarscov-19' OR 'sars-cov19' OR 'sars-cov-19' OR sarscov19 OR 'sarscov2' OR 'sarscov-2' OR 'sars-cov2' OR 'sars-cov-2' OR 'wn-cov' OR wncov):ti,ab)
3	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
4	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR 'food market*' OR 'seafood market*') AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
6	('serodiagnosis'/exp OR 'serology'/exp)
7	((('19S Gamma Globulin' OR '7S Gamma Globulin' OR Allerglobuline OR IgA OR IgG OR IgM OR Polyglobin OR Serodiagnos* OR Serologic*)):ti,ab)
8	OR/6-7
9	('delayed diagnosis'/exp OR 'diagnosis'/de OR 'diagnostic procedure'/de OR 'differential diagnosis'/exp OR 'early diagnosis'/exp OR 'examination'/exp OR 'laboratory diagnosis'/exp OR 'physical examination'/exp OR 'qualitative diagnosis'/exp OR 'quantitative diagnosis'/exp OR 'screening'/exp OR 'symptom assessment'/exp OR 'virus diagnosis'/exp)
10	((case* OR 'case finding' OR casefinding OR detect* OR diagnos* OR screen* OR test*):ti,ab)
11	OR/9-10
12	5 AND 8 AND 11
13	[english]/lim
14	12 AND 13
15	([animals]/lim NOT [humans]/lim)
16	14 NOT 15

17	('abstract report'/exp OR 'animal experiment'/exp OR 'book'/exp OR 'case finding'/exp OR 'case report'/exp OR 'case study'/exp OR 'conference paper'/exp OR 'editorial'/exp OR 'feasibility study'/exp OR 'in vitro study'/exp 'letter'/exp OR 'meta analysis'/exp OR 'meta analysis topic'/exp OR 'meta analysis (topic)'/exp OR 'note'/exp OR 'practice guideline'/exp OR 'review'/exp OR 'systematic review'/exp OR 'systematic review topic'/exp OR 'systematic review (topic)'/exp OR 'veterinary clinical trial'/exp OR 'veterinary study'/exp OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim OR [short survey]/lim OR meta*analys*:ti,ab OR (integrative NEAR/5 research NEAR/5 review*):ti,ab OR (methodologic* NEAR/5 overview*):ti,ab OR (methodologic* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 overview*):ti,ab OR (quantitativ* NEAR/5 review*):ti,ab OR (quantitativ* NEAR/5 synthesi*):ti,ab OR (research NEAR/5 integration):ti,ab OR (systematic* NEAR/5 overview*):ti,ab OR (systematic* NEAR/5 review*):ti,ab)
18	16 NOT 17
19	(([01-08-2022]/sd NOT [01-09-2022]/sd) AND [2022-2022]/py)
20	18 AND 19

Cochrane (Serology) SEARCH DATE: 01/01/2023	
Set #	Search Strategy
1	(MeSH descriptor: [COVID-19] explode all trees OR MeSH descriptor: [SARS-CoV-2] explode all trees)
2	((("2019 novel" OR "2019-ncov" OR 2019ncov OR corvid19 OR "corvid-19" OR cov19 OR covid19 OR covid2019 OR "covid 2019" OR "covid-19" OR "hcov-19" OR hcov19 OR ncorona* OR ncorono* OR "n-cov" OR "ncov-2019" OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncover OR ncovwuhan* OR "novel betacoronavirus" OR "Novel Coronavirus" OR "novel CoV" OR "sarscov-19" OR "sars-cov19" OR "sars-cov-19" OR sarscov19 OR "sarscov2" OR "sarscov-2" OR "sars-cov2" OR "sars-cov-2" OR "wn-cov" OR wncov):ti,ab)
3	((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)
4	(((((respiratory AND (condition* OR disease* OR illness* OR symptom*)) OR "food market*" OR "seafood market*") AND (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)
5	OR/1-4
6	MeSH descriptor: [COVID-19 Testing] explode all trees OR MeSH descriptor: [Immunoglobulin A] explode all trees OR MeSH descriptor: [Immunoglobulin G] explode all trees OR MeSH descriptor: [Immunoglobulin M] explode all trees OR MeSH descriptor: [Serologic Tests] explode all trees OR MeSH descriptor: [Serology] explode all trees

7	("19S Gamma Globulin" OR "7S Gamma Globulin" OR Allerglobuline OR IgA OR IgG OR IgM OR Polyglobin OR Serodiagnos* OR Serologic*):ti,ab
8	OR/6-7
9	MeSH descriptor: [Delayed Diagnosis] explode all trees
10	MeSH descriptor: [Diagnosis] this term only
11	MeSH descriptor: [Diagnosis, Differential] explode all trees
12	MeSH descriptor: [Diagnostic Techniques and Procedures] explode all trees
13	MeSH descriptor: [Early Diagnosis] explode all trees
14	Any MeSH descriptor in all MeSH products and with qualifier(s): [diagnosis - DI]
15	case* OR "case finding" OR casefinding OR detect* OR diagnos* OR screen* OR test*
16	OR/9-15
17	5 AND 8 AND 19
18	August 1-31, 2022
19	17 AND 18

Search Strategy Modification

<p>Pubmed</p> <p>("COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh])</p> <p>("2019 novel*" [tiab] OR "2019-ncov" [tiab] OR 2019ncov [tiab] OR covid19 [tiab] OR covid2019 [tiab] OR "covid 2019" [tiab] OR "covid-19" [tiab] OR "hcov-19" [tiab] OR hcov19 [tiab] OR "n-cov" [tiab] OR "ncov-2019" [tiab] OR ncov [tiab] OR ncov2019 [tiab] OR "novel betacoronavirus" [tiab] OR "Novel Coronavirus" [tiab] OR "novel CoV" [tiab] OR "sars-cov19" [tiab] OR "sars-cov-19" [tiab] OR sarscov19 [tiab] OR "sarscov2" [tiab] OR "sarscov-2" [tiab] OR "sars-cov2" [tiab] OR "sars-cov-2" [tiab])</p> <p>((epidem* [tiab] OR outbreak* [tiab] OR pandem* [tiab] OR wildlife* [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab]))</p> <p>((respiratory [tiab] AND (condition* [tiab] OR disease* [tiab] OR illness* [tiab] OR symptom* [tiab])) OR "food market*" [tiab] OR "seafood market*" [tiab]) AND (china* [tiab] OR chinese* [tiab] OR huanan* [tiab] OR hubei* [tiab] OR wuhan* [tiab]))</p>
<p>Embase</p> <p>('coronavirus disease 2019'/exp OR 'Severe acute respiratory syndrome coronavirus 2'/exp)</p> <p>((('2019 novel*' OR '2019-ncov' OR 2019ncov OR corvid19 OR 'corvid-19' OR cov19 OR covid19 OR covid2019 OR 'covid 2019' OR 'covid-19' OR 'hcov-19' OR hcov19 OR ncorona* OR ncorono* OR 'n-cov' OR 'ncov-2019' OR ncov OR ncov2019 OR</p>

<p>ncovchina* OR ncovchinese* OR ncovhubei* OR ncovor OR ncovwuhan* OR 'novel betacoronavirus' OR 'Novel Coronavirus' OR 'novel CoV' OR 'sarscov-19' OR 'sars-cov19' OR 'sars-cov-19' OR sarscov19 OR 'sarscov2' OR 'sarscov-2' OR 'sars-cov2' OR 'sars-cov-2' OR 'wn-cov' OR wncov):ti,ab)</p> <p>((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)</p> <p>((((respiratory NEAR/2 (condition* OR disease* OR illness* OR symptom*)) OR 'food market*' OR 'seafood market*') NEAR/10 (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)</p>
<p>Cochrane</p> <p>(MeSH descriptor: [COVID-19] explode all trees OR MeSH descriptor: [SARS-CoV-2] explode all trees)</p> <p>((('2019 novel*' OR '2019-ncov' OR 2019ncov OR corvid19 OR 'corvid-19' OR cov19 OR covid19 OR covid2019 OR 'covid 2019' OR 'covid-19' OR 'hcov-19' OR hcov19 OR ncorona* OR ncorono* OR 'n-cov' OR 'ncov-2019' OR ncov OR ncov2019 OR ncovchina* OR ncovchinese* OR ncovhubei* OR ncovor OR ncovwuhan* OR 'novel betacoronavirus' OR 'Novel Coronavirus' OR 'novel CoV' OR 'sarscov-19' OR 'sars-cov19' OR 'sars-cov-19' OR sarscov19 OR 'sarscov2' OR 'sarscov-2' OR 'sars-cov2' OR 'sars-cov-2' OR 'wn-cov' OR wncov):ti,ab)</p> <p>((epidem* OR outbreak* OR pandem* OR wildlife*) NEAR/1 (china* OR chinese* OR huanan*)):ti,ab)</p> <p>((((respiratory NEAR/2 (condition* OR disease* OR illness* OR symptom*)) OR 'food market*' OR 'seafood market*') NEAR/10 (china* OR chinese* OR huanan* OR hubei* OR wuhan*)):ti,ab)</p>

Table s3. QUADAS-2 Risk of Bias Assessment (for test accuracy studies)

Nº	Author year	Patient selection Risk of bias	Index test Risk of bias	Reference standard Risk of bias	Flow and timing Risk of bias
1.	Al Haddad 2021	High	Low	Low	Low
2.	Ali 2022	High	Low	Low	Low
3.	Aoki 2021	High	Low	Low	Low
4.	Bal 2021	High	Low	Low	Low
5.	Bond 2021	High	Low	Low	Low
6.	Boum 2021	High	Low	Low	Low
7.	Bryan 2020	High	High	Low	Low
8.	Buchholtz 2021	High	Low	Low	Low
9.	Bundschuh 2020	High	Low	Low	Low
10.	Buntinx 2020	High	Low	Low	Low
11.	Butterfield 2021	High	Low	Low	Low
12.	Catry 2021	High	Low	Low	Low
13.	Caturegli 2020	High	Low	Low	Low
14.	Chamkhi 2022	High	Low	Low	Low
15.	Chansaenroj 2021	High	Unclear	Low	Low
16.	Charlton 2020	High	Low	Low	Low

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17.	Charpentier 2020	High	Low	Low	Low
18.	Chen 2020	High	Low	Low	Low
19.	Chew 2020	High	Low	Low	Low
20.	Choe 2020	Low	Unclear	Low	Low
21.	Choi 2022	High	Low	Low	Low
22.	Cobb 2022	High	Low	Low	Low
23.	Conklin 2020	High	Unclear	Low	Low
24.	Cota 2020	High	Low	Low	Low
25.	Cs 2021	High	Low	low	Low
26.	Dellière 2020	High	Unclear	Low	Low
27.	Dortet 2020	High	Low	Low	Low
28.	Egger 2020	High	Low	Low	Low
29.	Escribano 2020	Low	Low	Low	Low
30.	Favresse 2021	High	Low	Low	Low
31.	Fischer 2021	High	Low	Low	Low
32.	Florin 2021	High	Low	Low	Low
33.	Fujigaki 2020	High	Low	Low	Low
34.	Gebrecherkos 2022	High	Low	Low	Low
35.	Grossberg 2021	High	Low	Low	Low
36.	Guedez-López 2020	High	Low	Low	Low

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37.	Harley 2020	High	Unclear	Low	Low
38.	Harrington 2021	High	Low	Low	Low
39.	Hibino 2022	High	Low	High	Low
40.	Higgins 2021	High	Low	Low	Low
41.	Hörber 2020	High	Low	Low	Low
42.	Hubbard 2021	High	Low	Low	Low
43.	Huber 2021	High	Low	High	Low
44.	Huyghe 2020	High	Low	Low	Low
45.	Igawa 2021	High	Low	Low	Low
46.	Imai 2020	High	Low	Low	Low
47.	Infantino 2020	High	Low	Low	Low
48.	Interiano 2021	Low	Low	Low	Low
49.	Jacot 2021	High	Low	Low	Low
50.	Jugwanth 2022	High	Low	Low	Low
51.	Jung 2020	High	Low	Low	Low
52.	Kim 2022	High	Low	Low	Low
53.	Kittel 2021	High	Low	Low	Low
54.	Kohmer 2020	High	Low	Low	Low
55.	Kubota 2021	High	Low	Low	Low
56.	Kulkarni 2021	High	Low	Low	Low

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57.	Lin 2021	High	Low	Low	Low
58.	Liu 2020	High	Low	Low	Low
59.	Lokida 2022	High	Low	Low	Low
60.	Lou 2020	High	Low	Low	Low
61.	Maine 2020	High	Low	Low	Low
62.	Maine 2022	High	Low	Low	Low
63.	Mairesse 2020	High	Low	Low	Low
64.	Mallon 2021	High	Low	Low	Low
65.	Manalac 2020	High	Low	Low	Low
66.	Marlet 2020	High	Low	Low	Low
67.	Martinaud 2020	High	Low	Low	Low
68.	Meng 2020	High	Low	Low	Low
69.	Merrill 2020	High	Low	Low	Low
70.	Montesinos 2020	High	Low	Low	Low
71.	Nakano 2021	High	Low	Low	Low
72.	Narasimhan 2021	High	Low	Low	Low
73.	Nicholson 2021	High	Low	Low	Low
74.	Nilles 2021	High	Low	Low	Low
75.	Nilsson 2021	High	Low	Low	Low
76.	Ong 2020	High	Low	Low	Low

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77.	Ou 2021	High	Low	Low	Low
78.	Ozturk 2021	High	Low	High	Low
79.	Paiva 2021	High	Low	Low	Low
80.	Pallett 2021	High	Low	Low	Low
81.	Pecoraro 2021	High	Low	High	Low
82.	Pegoraro 2021	High	Low	Low	Low
83.	Pérez-García 2020	High	Low	Low	Low
84.	Pérez-García 2021	High	Low	Low	Low
85.	Plaga 2021	High	Low	Low	Low
86.	Prazuck 2020	Low	Low	Low	Low
87.	Puschel 2021	High	Low	Low	Low
88.	Qiu 2020	High	Low	Low	Low
89.	Rostamzadeh 2021	High	Low	High	Low
90.	Saluzzo 2021	High	Low	Low	Low
91.	Şener 2022	High	Low	Low	Low
92.	Serrano 2020	High	Low	Low	Low
93.	Serre-Miranda 2021	High	Low	Low	Low
94.	Shen 2020	Low	Low	Low	Low
95.	Sisay 2021	High	Low	Low	Low
96.	Soleimani 2021	High	Low	Low	Low

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97.	Stein 2021	High	Low	Low	Low
98.	Suhandynata 2020	High	Low	Low	Low
99.	Tan 2020	High	Low	Low	Low
100.	Tan 2021	High	Low	Low	Low
101.	Tang 2020	High	Low	Low	Low
102.	Tanis 2021	High	Low	Low	Low
103.	Theel 2020	High	Low	Low	Low
104.	Therrien 2021	High	Low	Low	Low
105.	Traugott 2020	High	Low	Low	Low
106.	Tré-Hardy 2021	High	High	Low	Low
107.	Turbett 2020	High	Low	Low	Low
108.	Van Elslande 2020	High	Low	Low	Low
109.	Van Elslande 2022	High	Low	Low	Low
110.	Vauloup-Fellous 2021	High	Low	High	Low
111.	Velay 2020	High	Low	Low	Low
112.	Wakita 2021	High	Low	Low	Low
113.	Wehrhahn 2021	High	Low	Low	Low
114.	Whitman 2020	High	Low	Low	Low
115.	Wolf 2020	High	Low	Low	Low
116.	Wolff 2020	High	Low	Low	Low

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117.	Yamamoto 2022	High	Low	Low	Low
118.	Yang 2020	High	Low	Low	Low
119.	Yang 2021	High	Low	Low	Low
120.	Yassine 2021	High	Low	Low	Low
121.	Yun 2021	High	Low	Low	Low
122.	Zervou 2021	High	Low	Low	Low

Table s4. ROBINS-I Risk of Bias Assessment (for non-test accuracy comparative studies)

N ^o	Author year	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
1.	Addetia 2020	Critical	Serious	Low	Low	Low	Low	Low
2.	Aldridge 2022	Serious	Low	Low	Low	Low	Low	Moderate
3.	Ali 2021	Critical	Critical	Low	Low	Low	Low	Low
4.	Anand 2022	Serious	Serious	Low	Low	Low	Moderate	Low
5.	Asderakis 2022	Moderate	Serious	Low	Moderate	Low	Moderate	Moderate
6.	Atti 2022	Moderate	Critical	Low	Low	Moderate	Low	Low
7.	<u>Bergwerk</u> , 2021	Serious	Moderate	Low	Low	Low	Low	Low
8.	Gilbert, 2021	Low	Low	Low	Low	Low	Low	Low
9.	Hanrath 2020	Critical	Critical	Low	Low	Serious	Low	Moderate
10.	Hønge 2022	Critical	Critical	Low	Low	Low	Low	Moderate
11.	Lumley 2021	Critical	Critical	Low	Low	Low	Low	Moderate
12.	McGee 2022	Serious	Moderate	Low	low	Low	Low	Moderate
13.	Murt 2022	Critical	Serious	Low	Low	Low	Low	Low
14.	Ollila 2022	Moderate	Serious	Low	Low	Low	Low	Low
15.	Patnaik 2022	Critical	Serious	Low	Low	Low	Low	Moderate

Table s5. Characteristics of the included test accuracy studies

#	Study	Patient with COVID-19	Control group (if applicable)	Serology Assay(s)	Reference Standard
1.	<p>Author, year: Al Haddad 2021[1]</p> <p>Country: Lebanon</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 127</p> <p>Patient selection: we collected 73 sera from patients who were diagnosed with Covid-19 by RT-PCR.</p> <p>Age: mean 54</p> <p>Gender (%female): NR</p>	<p>Patient selection: Of the latter, 54 were random anonymous control samples that originated from donors who had donated blood at our blood bank before July 2019. To assess the cross reaction of any viruses or autoimmune diseases with the assays being studied.</p> <p>Age: mean 49</p> <p>Gender (%female): NR</p>	<p>Test name 1: Maglumi</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: we collected 73 sera from patients who were diagnosed with Covid-19 by RT-PCR.</p>
2.	<p>Author, year: Ali 2022[2]</p> <p>Country: Libya</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 95</p> <p>Patient selection: The research was carried out at Sebha University, Faculty of Science from June 4th to August 28th, 2020, with a total of 95 patients, including 67 COVID-19 patients recorded at Respiratory Clinic, Sebha, Libya. Positive results for COVID-19 were confirmed as those obtained through real time (RT)-PCR detection</p> <p>Age: NR</p> <p>Gender (%female): 64%</p>	<p>Patient selection: 28 healthy people were chosen as controls</p> <p>Age: NR</p> <p>Gender (%female): 75%</p>	<p>Test name: STANDARD Q</p> <p>Platform: RCIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: 67 COVID-19 patients recorded at Respiratory Clinic, Sebha, Libya. Positive results for COVID-19 were confirmed as those obtained through real time (RT)-PCR detection</p>

		Collection start date: 6/4/2020 Collection end date: 8/28/2020			
3.	Author, year: Aoki 2021[3] Country: Japan Study Design: Case Control	Total Number of patients: 754 Patient selection: In total, 206 samples from 70 cases, including multiple samples available from 32 cases, were collected at Toho University Omori Medical Center and the National Hospital Organization Tokyo Medical Center Age: NR Gender (%female): NR Collection start date: 3/1/2020 Collection end date: 5/1/2020	Patient selection: We used three groups of samples for specificity evaluation. The first group comprised 166 samples from 109 cases of suspected COVID-19 judged to have a viral load below the LOD of RT-PCR for SARS-CoV-2. These samples were collected at Toho University Omori Medical Center Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: These samples were confirmed as positive for SARS-CoV-2 by RT-PCR.
4.	Author, year: Bal 2021[4] Country: France Study Design: Case Control	Total Number of patients: 577 Patient selection: A prospective longitudinal cohort study was conducted at the laboratory associated with the National reference center for respiratory viruses (University Hospital of Lyon, France) (21). Healthcare workers (HCW) with symptoms suggesting a SARS-CoV-2 infection requiring a RT-PCR test were included	Patient selection: 69 prepandemic sera (collected between April and July 2019) from 30 healthy volunteers (52% females, median age of 28 y, interquartile range (IQR): 21–34), 30 patients with autoimmune disorders, and 9 patients with a positive serological result for M. pneumonia.	Test name 1: Wantai Platform: ELISA EUA certified: Yes CE certified: Yes Test name 2: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes	Reference: For each test, the clinical sensitivity was estimated weekly after symptom onset considering SARS-CoV-2 RT-PCR results as the gold standard.

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		Age: NR Gender (%female): NR	Age: NR Gender (%female): NR	CE certified: Yes Test name 3: Bio-Rad Platelia Platform: ELISA EUA certified: Yes CE certified: Yes	
5.	Author, year: Bond 2021[5] Country: Australia Study Design: Case Control	Total Number of patients: 362 Patient selection: 131 SARS-CoV-2 RT-PCR positive patients Age: NR Gender (%female): NR Collection start date: 4/27/2020 Collection end date: 10/29/2020	Patient selection: 200 pre-pandemic samples; and 31 potentially cross-reactive sera collected from patients with other acute infections collected before December 2019 Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: SARS-CoV-2 RNA was detected by at least two of three assays, specifically the Coronavirus Typing assay (AusDiagnostics, Australia), Respiratory Pathogens 12-well assay (AusDiagnostics), the Xpert Xpress SARS-CoV-2 (Cepheid, USA) or an in-house real-time assay

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6.	<p>Author, year: Boum 2021[6]</p> <p>Country: Cameroon</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 447</p> <p>Patient selection: In this clinical, prospective, diagnostic accuracy study, we evaluated the performance characteristics of five SARS-CoV-2 rapid diagnostic tests in two groups of Cameroonian adult participants: 570 (48%) symptomatic individuals suspected of having SARS-CoV-2 or already on treatment and 625 (52%) asymptomatic individuals presenting for voluntary SARS-CoV-2 screening or referred for testing through contact tracing. 347 (29%) tested SARS-CoV-2 PCR-positive.</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 6/2/2020</p> <p>Collection end date: 8/20/2020</p>	<p>Patient selection: historical samples collected and stored 2 years before the pandemic</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Innovita</p> <p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: gold-standard PCR testing</p>
7.	<p>Author, year: Bryan 2020[7]</p> <p>Country: United States</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 125</p> <p>Patient selection: To determine assay sensitivity, we used serum specimens from a series of 125 patients who tested RT-PCR positive for SARS-CoV-2 and for whom 689 excess serum specimens comprising 415 unique patient follow-up days were available. The vast majority of these patients were hospitalized at the</p>	<p>Patient selection: To determine assay specificity, we used 1,020 deidentified serum specimens from 1,010 different individuals sent to our laboratory for herpes simplex virus (HSV) Western blot serology in 2018 and 2019, before SARS-CoV-2 was</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: To determine assay sensitivity, we used serum specimens from a series of 125 patients who tested RT-PCR positive for SARS-CoV-2</p>

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		<p>University of Washington Medical Center–Northwest Campus in Seattle, WA, between March and April 2020.</p> <p>Age: range 20->90</p> <p>Gender (%female): 42</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 4/1/2020</p>	<p>thought to be circulating in Washington</p> <p>Age: NR</p> <p>Gender (%female): NR</p>		
8.	<p>Author, year: Buchholtz 2021[8]</p> <p>Country: Germany</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 267</p> <p>Patient selection: PCR-positive clinical cohort: Samples from 29 patients, admitted to the hospital of LMU Munich with acute COVID-19 confirmed by positive PCR were collected over time from leftover material of samples submitted to our Institute for routine laboratory diagnostics</p> <p>Age: median 71</p> <p>Gender (%female): 28.50%</p>	<p>Patient selection: Pre-COVID-19 cohort: Samples from 238 healthy pre-COVID-19 subjects were collected from 04/2016 until 10/2019 as part of the Munich Study on Biomarker Reference Values</p> <p>Age: range 18-80</p> <p>Gender (%female): NR</p>	<p>Test name 1: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Roche Elecsys</p> <p>Platform: ECLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: COVID-19 confirmed by positive PCR were collected over time</p>
9.	<p>Author, year: Bundschuh 2020[9]</p>	<p>Total Number of patients: 264</p> <p>Patient selection: 64 patients (53 males, 11 females) with SARS-CoV-2 RT-PCR</p>	<p>Patient selection: cohort of 200 healthy blood donors</p>	<p>Test name: EDI</p> <p>Platform: ELISA</p>	<p>Reference: SARS-CoV-2 RT-PCR confirmed COVID-19 with serial blood samples at</p>

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	Country: Austria Study Design: Case Control	confirmed COVID-19 with serial blood samples Age: Median: 65 years Gender (%female): 17.20% Collection start date: 3/15/2020 Collection end date: 4/10/2020	Age: NR Gender (%female): NR	EUA certified: No CE certified: Yes	different time points from symptom onset
10.	Author, year: Buntinx 2020[10] Country: Belgium Study Design: Case Control	Total Number of patients: 289 Patient selection: he total population consisted of 130 nursing home residents and 112 staff members. Some residents were not tested because at the time of the sampling they were either in hospital or deceased. Age: The mean age is 86 years. Gender (%female): NR Collection start date: 4/14/2020 Collection end date: 4/16/2020	Patient selection: 103 control samples as described previously (Table 1) [10,11]. Age: NR Gender (%female): NR	Test name: SureScreen Platform: LFIA EUA certified: No CE certified: Yes	Reference: RT-PCR tests were performed by local laboratories in accordance with the WHO guide lines on nasopharyngeal swabs sampled by the GP or the CRA
11.	Author, year: Butterfield 2021[11] Country: Jamaica Study Design: Case Control	Total Number of patients: 159 Patient selection: 42 blood samples collected in tubes without coagulant were obtained from 37 consenting persons (5 persons were sampled at two different time points) testing SARS-CoV-2 real-time PCR positive at the Jamaica	Patient selection: Residual 2018–2019 serum samples from 122 different patients and testing positive for antibodies to a wide range of viral infections or from healthy donors were identified from the University of the West	Test name: Abbott CoV-2 IgM (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: Samples were collected 6–103 days after disease onset for symptomatic persons and 20–69 days after a positive real-time PCR test for asymptomatic persons

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		National Influenza Centre using the Corman et al. method Age: NR Gender (%female): NR	Indies Virology Laboratory to assess diagnostic specificity. Age: NR Gender (%female): NR		
12.	Author, year: Catry 2021[12] Country: Belgium Study Design: Case Control	Patient selection: at CHU UCL Namur hospital during the COVID-19 pandemic. All individuals considered in this study were confirmed positive for COVID-19 infection by RT-qPCR targeting SARS-CoV-2 (Allplex™ 2019-nCoV Assay, Seegene) performed on nasopharyngeal swab samples and admitted in our hospital. Age: NA Gender (%female): NA Collection start date: 3/18/2020 Collection end date: 5/1/2020	Patient selection: SARS-CoV-2-negative control sera were thawed from a collection stored at -20 °C before January 2020 (preceding COVID-19 outbreak in Belgium). A total of 90 sera from immune or infected patients with positive Ab for various viruses Age: NA Gender (%female): NA	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CLIA EUA certified: No CE certified: Yes	Reference: confirmed positive for COVID-19 infection by RT-qPCR targeting SARS-CoV-2 (Allplex™ 2019-nCoV Assay, Seegene)
13.	Author, year: Caturegli 2020[13] Country: USA Study Design: Case Control	Total Number of patients: 876 Patient selection: 308 obtained longitudinally from 60 COVID-19 case patients Age: 59 (48–70) Gender (%female): 18%	Patient selection: The 513 persons in the laboratory control group were 160 healthy laboratory employees and 353 patients with a polyclonal activation of the antibody response (28). The latter subset was composed of 101 persons	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: using NAAT of nasopharyngeal swab

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		Collection start date: 3/11/2020 Collection end date: 4/12/2020	positive for IgG antibodies against Epstein–Ba Age: NR Gender (%female): NR		
14.	Author, year: Chamkhi 2022[14] Country: Tunisia Study Design: Case Control	Total Number of patients: 701 Patient selection: 443 patients hospitalized for moderate to critical COVID-19 in the pulmonology, COVID-19 (temporary) and intensive care unit (ICU) departments of Charles Nicolle Hospital in Tunis Age: mean 60.59 ± 16.29 years Gender (%female): 43.60% Collection start date: 3/1/2020 Collection end date: 4/1/2021	Patient selection: Pre-pandemic serum samples were obtained in 2018 from 108 healthy subjects. Controls were adult blood donors matched in age, gender, and ethnicity with the COVID-19 patients. Ethnicity (Tunisian) of both patients and controls was determined by an oral survey Age: NR Gender (%female): NR	Test name: Vidas BioMerieux Platform: FEIA EUA certified: Yes CE certified: Yes	Reference: Nasopharyngeal sampling for RT-PCR testing was performed for all patients. In patients with a negative RT-PCR result, chest computerized tomography (CT) scan was carried out.
15.	Author, year: Chansaenroj 2021[15] Country: Thailand Study Design: Case Control	Total Number of patients: NR Patient selection: Samples from all 245 patients (138 from the National Blood Center, 107 from Bangkok Metropolitan Administration Hospital) were obtained during the period between COVID-19 symptom onset and serum sample acquisition for serology testing	Patient selection: NR Age: NR Gender (%female): NR	Test name 1: STANDARD Q Platform: RCIA EUA certified: Yes CE certified: Yes	Reference: SARS-CoV-2 infection had been confirmed via real-time RT-PCR of nasal swab specimens or who had a previous SARS-CoV-2-positive diagnostic test result in their medical record from

		Age: NR Gender (%female): NR Collection start date: 3/1/2020 Collection end date: 10/1/2020		Test name 2: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	the hospital and public health center
16.	Author, year: Charlton 2020[16] Country: Canada Study Design: Case Control	Total Number of patients: 78 Patient selection: To develop a panel of positive sera from patients with COVID-19, serum samples were collected from hospitalized patients confirmed to be positive for SARS-CoV-2 upon nasopharyngeal swab or endotracheal aspirate testing by rRT-PCR. Age: median 73 Gender (%female): 43	Patient selection: Negative samples were retrieved from bio-banked sera stored at the public health laboratory (Alberta Precision Laboratories) in Alberta collected before 1 November 2019 Age: NR Gender (%female): NR	Test name 1: Innovita Platform: LFIA EUA certified: No CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: To develop a panel of positive sera from patients with COVID-19, serum samples were collected from hospitalized patients confirmed to be positive for SARS-CoV-2 upon nasopharyngeal swab or endotracheal aspirate testing by rRT-PCR.
17.	Author, year: Charpentier 2020[17] Country: France Study Design: Case Control	Total Number of patients: 262 Patient selection: collected in the Virology Laboratory of Bichat-Claude Bernard and Saint-Louis University-Hospitals both in Paris, France. Eighty-eight serum samples were collected	Patient selection: We constituted a negative panel of 120 sera, all collected before November 2019, to assess the specificity Age: NA	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: confirmed COVID-19 diagnosis by a positive nasopharyngeal sample RT-PCR.

		from 54 patients with a confirmed COVID-19 diagnosis Age: Median 52 (range: 27–80) Gender (%female): 30.70%	Gender (%female): NA		
18.	Author, year: Chen 2020[18] Country: Taiwan Study Design: Case Control	Total Number of patients: 267 Patient selection: A total of 346 serum samples were obtained from the 74 patients with COVID-19 (the number of samples obtained from each individual patient ranged from 1 to 38 samples; median, 4 samples) at different time points during the disease course Age: 38.5 ± 16.2 Gender (%female): 44.60% Collection start date: 1/23/2020 Collection end date: 5/31/2020	Patient selection: 194 control serum samples to evaluate the cross-reactivity and diagnostic specificity of the five antibody tests in this study: 70 from hospitalized patients with an acute respiratory infection (ARI) who tested negative ≥2 times using SARS-CoV-2 qRT-PCR a Age: NA Gender (%female): NA	Test name 1: Abbott CoV-2 IgG (ARCHITECT) Platform: CLIA EUA certified: Yes CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: qRT-PCR-confirmed COVID-19 patients
19.	Author, year: Chew 2020[19] Country: Singapore Study Design: Case Control	Total Number of patients: 340 Patient selection: 177 - We prospectively identified confirmed COVID-19 patients presenting at and admitted to our institution from 30th March 2020 to 15th May 2020. Patients were selected on the basis of a positive SARS-CoV-2 rRT-PCR from a respiratory sample.	Patient selection: 163 non-COVID-19 patients, Negative controls were samples taken from patients prior to December 2019 Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: Patients were selected on the basis of a positive SARS-CoV-2 rRT-PCR from a respiratory sample

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		Age: NR Gender (%female): NR Collection start date: 3/30/2020 Collection end date: 5/15/2020			
20.	Author, year: Choe 2020[20] Country: Korea Study Design: Cross-sectional study	Total Number of patients: 149 Patient selection: 70 - Participants in this study were divided into two groups: those with positive RT-PCR (n = 70) findings for SARS CoV2. The positive RTPCR group comprised patients being treated in the quarantine ward of our hospital after confirming infection with COVID-19. 79 - The negative RTPCR group contained subjects with a negative result obtained on RT-PCR in screening for COVID-19. Age: 67.9 ± 15.6 Gender (%female): 57.10% Collection start date: 3/20/2020 Collection end date: 4/8/2020	Patient selection: NA Age: NA Gender (%female): NA	Test name: PCL Platform: RCIA EUA certified: No CE certified: Yes	Reference: RT-PCR as a reference assay
21.	Author, year: Choi 2022[21] Country: South Korea	Total Number of patients: 988 Patient selection: 199 COVID-19-positive patients confirmed using RT-PCR between March and November 2020	Patient selection: 587 COVID19-negative patients with no history of COVID-19 or any epidemiological relationship with COVID-19	Test name 1: STANDARD Q Platform: LFIA EUA certified: No	Reference: confirmed using RT-PCR

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	Study Design: Case Control	Age: median age (IQR), 56 (38–67) years Gender (%female): 60% Collection start date: 3/1/2020 Collection end date: 11/1/2020	between June 2019 and October 2020 Age: median age (IQR), 54 (38–68) years Gender (%female): 62%	CE certified: Yes Test name 2: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes Test name 3: Siemens ADVIA Centaur Platform: CLIA EUA certified: Yes CE certified: Yes	
22.	Author, year: Cobb 2022[22] Country: USA Study Design: Case Control	Total Number of patients: 244 Patient selection: This study was approved by the Washington University Institutional Review Board. All specimens were clinical remnants collected in EDTA plasma tubes. One hundred twenty specimens were from patients presenting symptomatic and confirmed positive for COVID-19 by EUA Cepheid Xpert Xpress SARS-CoV-2 test Age: 64.8 years (range 40–90)	Patient selection: 77 specimens from patients confirmed negative by EUA Cepheid Xpert Xpress SARS-CoV-2 test and clinically adjudicated as nonCOVID-19 patients, and 47 prepandemic specimens were used. Age: NR Gender (%female): NR	Test name: ADEXUSDx Platform: LFA EUA certified: Yes CE certified: Yes	Reference: confirmed positive for COVID-19 by EUA Cepheid Xpert Xpress SARS-CoV-2 test

		Gender (%female): 42%			
23.	Author, year: Conklin 2020[23] Country: Study Design:	Total Number of patients: 107 Patient selection: To determine the sensitivity of antibody testing by duration of infection, plasma specimens obtained from individuals with known date of symptom onset who had serial specimens were tested. Samples (n = 272) came from 47 hospitalized SARS-CoV-2 RT-PCR-confirmed patients and were used to determine the sensitivity by duration of infection for a subset of SARS-CoV-2 point-of-care antibody test kits evaluated. Age: 62 (44 - 80) Gender (%female): 38%	Patient selection: Specificity of LFAs was assessed with 60 samples from prepandemic time points of individuals known to be uninfected by SARS-CoV-2 . These samples came from a study of patients presenting to the Johns Hopkins Hospital Emergency Department with symptoms of a respiratory infection Age: NR Gender (%female): NR	Test name: ALLTEST Platform: LFIA EUA certified: Yes CE certified: Yes	Reference: RT-PCR positive for SARS-CoV-2
24.	Author, year: Cota 2020[24] Country: Brazil Study Design: Case Control	Total Number of patients: 289 Patient selection: This panel-based study comprised 289 serum samples from 173 symptomatic patients with confirmed SARS-CoV-2 infection Age: Mean: 47.5 years Gender (%female): 52.60% Collection start date: 4/21/2020 Collection end date: 6/10/2020	Patient selection: 116 negative controls. The negative control sera were all obtained before January 2020, which marked the introduction of the new coronavirus in Brazil, from patients with serological markers for other infectious or non-infectious diseases Age: NR Gender (%female): NR	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: All the cases (SARS-CoV-2 positive) were confirmed by RT-PCR testing of nasopharyngeal or oropharyngeal swabs

25.	<p>Author, year: Cs 2021[25]</p> <p>Country: Singapore</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 381</p> <p>Patient selection: in subjects who tested positive for SARS-CoV-2 on RT-PCR from April to June 2020 were recruited as cases (N = 133) (see Fig. 1). 78 RT-PCR positive samples were repeat sample from 27 patients.</p> <p>Age: 26 to 98 mean: (51.0 ± 17.7)</p> <p>Gender (%female): 18.80%</p> <p>Collection start date: 4/1/2020</p> <p>Collection end date: 6/1/2020</p>	<p>Patient selection: Residual leftover sera were used in this study. Two-hundred pre-pandemic samples from a staff health screening (HS) program in 2018 served as controls.</p> <p>Age: 25 to 85 mean: (47.2 ± 12.7)</p> <p>Gender (%female): 79.10%</p>	<p>Test name: Abbott CoV-2 IgM (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: tested positive for SARS-CoV-2 on RT-PCR</p>
26.	<p>Author, year: Dellièrè 2020[26]</p> <p>Country: France</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 144</p> <p>Patient selection: Serum samples (n 106) were tested from 102 patients with positive SARS-COV-2 RT-PCR (Cobas SARS-CoV-2 test; Roche, Meylan, France) and at least 4 days (4 to 40; median, 18) after the onset of symptoms or positive PCR for asymptomatic patients</p> <p>Age: mean 52</p> <p>Gender (%female): NR</p>	<p>Patient selection: Negative samples tested (n 42) were acquired during the prepandemic period from routine occupational health patients with no known disease (n 14) or hospitalized patients (n 28) with a previous pulmonary infection with endemic coronavirus or rhinovirus</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Healgen</p> <p>Platform: LFIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: Serum samples (n 106) were tested from 102 patients with positive SARS-COV-2 RT-PCR (Cobas SARS-CoV-2 test; Roche, Meylan, France) and at least 4 days (4 to 40; median, 18) after the onset of symptoms or positive PCR for asymptomatic patients</p>

27.	<p>Author, year: Dortet 2020[27]</p> <p>Country: France</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 413</p> <p>Patient selection: 256 sera were collected from 101 RT–PCR confirmed patients during COVID-19 specific consultations or while patients were in the emergency department.</p> <p>Age: median age was 58 years (IQR, 35–61)</p> <p>Gender (%female): 40.59%</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 3/23/2020</p>	<p>Patient selection: A total of 50 samples were also collected to assess specificity: 24 sera collected from September–October 2017, before the COVID pandemic, 4 from patients with respiratory symptoms that were RT–PCR negative for SARS-CoV-2 but positive for common coronavirus</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: NG-TEST</p> <p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: Nasopharyngeal samples (eSwabs™–Virocult, Copan, Italy) were collected from all patients with COVID-19 symptoms. Real-time RT–PCR targeting RNA-dependent RNA polymerase and E genes were used to detect the presence of SARS-CoV-2</p>
28.	<p>Author, year: Egger 2020[28]</p> <p>Country: Austria</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 520</p> <p>Patient selection: ARS-CoV-2 RT-PCR confirmed COVID-19 patients with serial blood samples (n = 104) at different time points from symptom onset</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 200 Healthy blood sample collected prior to COVID-19 in addition to 256 ICU patients' blood sample collected prior to COVID19 outbreak</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: EDI</p> <p>Platform: ELISA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p> <p>Test name 2: Roche Elecsys</p> <p>Platform: ECLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: RT-PCR confirmed COVID-19 patients</p>

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29.	<p>Author, year: Escribano 2020[29]</p> <p>Country: Spain</p> <p>Study Design: Cohort</p>	<p>Total Number of patients: 65</p> <p>Patient selection: Cohort 1 (n = 65) included patients with clinical suspicion of active COVID-19 who attended the emergency department on March 30, 2020.</p> <p>Age: median age of 56 years</p> <p>Gender (%female): 40%</p> <p>Collection start date: 3/15/2020</p> <p>Collection end date: 4/15/2020</p>	<p>Patient selection: NA</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: classified considering PCR results on nasopharyngeal samples</p>
30.	<p>Author, year: Favresse 2021[30]</p> <p>Country: Belgium</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 237</p> <p>Patient selection: 96</p> <p>Age: mean age: 63 years</p> <p>Gender (%female): 46.90%</p> <p>Collection start date: 3/21/2020</p> <p>Collection end date: 5/25/2020</p>	<p>Patient selection: Non-SARS-CoV-2 sera (n = 141) with a potential cross-reaction to SARS-CoV-2 immunoassays were included in the specificity analysis</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Roche Elecsys</p> <p>Platform: ECLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: OVID-19 patients confirmed positive for SARS-CoV-2 by RT-PCR</p>
31.	<p>Author, year: Fischer 2021[31]</p> <p>Country: USA</p>	<p>Total Number of patients: 278</p> <p>Patient selection: Plasma samples from subjects with confirmed, symptomatic COVID-19 infections (WU-350) were</p>	<p>Patient selection: 168 archived, de-identified pre-pandemic samples from the US</p>	<p>Test name 1: Innovita</p> <p>Platform: LFIA</p> <p>EUA certified: Yes</p>	<p>Reference: Cases confirmed by RT-PCR</p>

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	Study Design: Case Control	collected at Barnes-Jewish Hospital, an affiliated teaching hospital of Washington University School of Medicine. Age: NR Gender (%female): NR Collection start date: 3/1/2020 Collection end date: 5/1/2020	(80 samples) and Africa (88 samples) Age: NR Gender (%female): NR	CE certified: Yes Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	
32.	Author, year: Florin 2021[32] Country: Belgium Study Design: Case Control	Total Number of patients: 146 Patient selection: For sensitivity, 175 follow-up routine serum specimens from 58 hospitalized patients with confirmed detection of SARS-CoV-2 RNA by RT-PCR on nasopharyngeal swab were measured. Age: median 80 Gender (%female): NR	Patient selection: specificity was evaluated using residual pre-pandemic serum specimens from healthy volunteers (n = 34) and random patients (n = 22). In addition, specimens from patients with potential cross-reacting antibodies, including antinuclear antibodies (n = 5) Age: NR Gender (%female): NR	Test name: Siemens CV2G Platform: CLIA EUA certified: Yes CE certified: Yes	Reference: patients (median age 80 years) with confirmed detection of SARS-CoV-2 RNA by RT-PCR on nasopharyngeal swab were measured
33.	Author, year: Fujigaki 2020[33] Country: Japan	Total Number of patients: 129 Patient selection: 99 serum samples collected from 29 patients diagnosed	Patient selection: 100 serum samples collected from 100 healthy volunteers in 2017 as negative controls.	Test name: ALLTEST Platform: LFIA EUA certified: No	Reference: All patients were confirmed as COVID-19 cases by RT-PCR assay of nasopharyngeal swab

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	Study Design: Case Control	with coronavirus disease 2019 (COVID-19) Age: Mean: 52.9 years Gender (%female): 51.70% Collection start date: 2/28/2020 Collection end date: 4/15/2020	Age: Mean: 50.7 years Gender (%female): 48%	CE certified: Yes	specimens at the time of or prior to admission.
34.	Author, year: Gebrecherkos 2022[34] Country: Ethiopia Study Design: Case Control	Total Number of patients: 252 Patient selection: They were recruited from Mekelle University College of Health Sciences (Kuyha COVID-19 Isolation and Treatment Center), Mekelle City, Northern Ethiopia, in a prospective fashion Age: median 33 Gender (%female): 23.50% Collection start date: 7/15/2020 Collection end date: 10/28/2020	Patient selection: For determining specificity, RT-PCR negative specimens (n = 100) were obtained during COVID-19 pandemic (August and September 2020) from individuals not suspected of SARS-CoV-2 infection. In addition, pre-pandemic specimens (n = 50) collected in 2017 Age: NR Gender (%female): NR	Test name 1: Innovita Platform: LFIA EUA certified: Yes CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: SARS-CoV-2 infection was confirmed by RT-PCR on samples obtained from nasopharyngeal swabs, as described previously
35.	Author, year: Grossberg 2021[35] Country: USA Study Design: Case Control	Total Number of patients: 5229 Patient selection: RT-PCR-confirmed COVID-19-positive Age: NR	Patient selection: COVID-19-negative (n = 296) patients. In addition, serum samples from healthy controls (n = 4502) and nonCOVID-19 disease controls (n = 128) were also used which	Test name: Vibrant Platform: CLIA EUA certified: Yes CE certified: No	Reference: RT-PCR-confirmed

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		Gender (%female): NR	were collected prior to the COVID-19 outbreak. Age: NA Gender (%female): NA		
36.	Author, year: Guedez-López 2020[36] Country: Spain Study Design: Case Control	Total Number of patients: 165 Patient selection: 145 Age: NA Gender (%female): 66.90% Collection start date: 3/8/2020 Collection end date: 4/2/2020	Patient selection: 20 serum samples from 2018 included as negative control Age: NR Gender (%female): NR	Test name: Sienna Platform: LFIA EUA certified: Yes CE certified: Yes	Reference: RT-qPCR has been considered the reference for the evaluation of the ICT strip assays.
37.	Author, year: Harley 2020[37] Country: United States Study Design: Case Control	Total Number of patients: 667 Patient selection: A total of 103 residual plasma samples were obtained from 62 patients with confirmed SARS-CoV-2 infections (i.e., a positive SARS-CoV-2 PCR diagnostic test); 50 samples were obtained from 11 hospitalized patients to observe dynamic antibody expression (pseudoseroconversion), and 53 additional samples were obtained from 51 unique patients at a single time point after confirmed SARS-CoV-2 infection. Age: NR	Patient selection: Two sources of pre-COVID-19 samples were used: (i) 30 plasma samples donated to a Wisconsin tissue bank between April 2015 and September 2019, 16 of which were obtained from cord blood, and (ii) 534 plasma samples from patients presenting to a Southern California emergency department collected in June 2020. Age: unclear	Test name: Abbott CoV-2 IgG (Alinity) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: A total of 103 residual plasma samples were obtained from 62 patients with confirmed SARS-CoV-2 infections (i.e., a positive SARS-CoV-2 PCR diagnostic test)

		Gender (%female): NR Collection start date: 4/1/2015 Collection end date: 9/1/2019	Gender (%female): NR		
38.	Author, year: Harrington 2021[38] Country: United Kingdom Study Design: Case Control	Total Number of patients: 91 Patient selection: A total sample set of 388 samples from 41 patients was available for testing. These samples were taken between March and June 2020. Sample collection date postsymptom onset ranged 1 to 120 days Age: Mean: 65 years Gender (%female): 43.90% Collection start date: 3/1/2020 Collection end date: 5/1/2020	Patient selection: A panel of 50 prepandemic serum samples collected July to September 2018 was tested as negative controls Age: NR Gender (%female): NR	Test name 1: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: For the sensitivity calculations a larger sample set was identified by cross-matching a list of current inpatients in our hospital trust who were admitted 7 to 14 days previously against a list of all confirmed COVID-19 patients
39.	Author, year: Hibino 2022[39] Country: Japan Study Design: Case Control	Total Number of patients: 2014 Patient selection: We collected and tested 1282 serum samples from 286 patients with COVID-19 during hospitalization and outpatient follow-up, and 227 patients had sequential samples available. Thus, the analysis was performed on samples collected from these 227 patients (n ¼ 1154), excluding	Patient selection: As negative controls, we used surplus serum samples that were collected during the annual medical checkups of medical staff at Shonan Fujisawa Tokushukai Hospital to determine the validity of the assays. The checkups were	Test name 1: Abbott CoV-2 IgM (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: The standard test for diagnosing acute-phase SARS-CoV-2 infection is a genetic test that detects SARSCoV-2 RNA by reverse transcription polymerase chain

		<p>duplicate samples collected from the same patient during the same time period</p> <p>Age: 66 (51-77)</p> <p>Gender (%female): 48%</p> <p>Collection start date: 2/1/2020</p> <p>Collection end date: 10/1/2020</p>	<p>conducted between June 1, 2020 and July 30, 2020</p> <p>Age: median age, 34 years [IQR 28-46 years]</p> <p>Gender (%female): 71%</p>	<p>Test name 2: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 3: Siemens COV2T</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>reaction (RT-PCR) or loop-mediated isothermal amplification (LAMP) in nasal or pharyngeal swabs</p>
40.	<p>Author, year: Higgins 2021[40]</p> <p>Country: Canada</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 282</p> <p>Patient selection: 175 patients that were confirmed positive for SARS-CoV-2 infection by PCR testing within the previous 0–73 days.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 07 patients that were positive for viruses other than SARS-CoV-2 (e.g. hepatitis A, hepatitis B, hepatitis C, human immunodeficiency virus, rubella, Epstein-Barr virus, cytomegalovirus, respiratory syncytial virus, enterovirus, rhinovirus, and influenza A</p> <p>Age: NR</p>	<p>Test name 1: Abbott CoV-2 IgM (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p>	<p>Reference: plasma samples were collected from 175 patients that were confirmed positive for SARS-CoV-2 infection by PCR testing within the previous 0–73 days</p>

			Gender (%female): NR	EUA certified: Yes CE certified: Yes	
41.	Author, year: Hörber 2020[41] Country: Study Design:	Total Number of patients: 181 Patient selection: Routine blood samples (n=186) of hospitalized COVID-19 patients (n=58) were used for serial antibody measurements. Age: NR Gender (%female): NR	Patient selection: COVID-19 negative control samples were all obtained before the beginning of the pandemic and comprises intensive care patients (n=88). In addition, potential cross-reactive antibodies (n=35) were investigated using samples from patients with laboratory confirmed acute infections Age: NR Gender (%female): NR	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: Diagnostic sensitivity was determined using samples from patients with RT-PCR confirmed COVID-19 disease at different time points
42.	Author, year: Hubbard 2021[42] Country: USA Study Design: Case Control	Total Number of patients: 407 Patient selection: 407 remnant serum and lithium heparin plasma specimens collected in gel-separator tubes for clinical purposes from hospitalized patients with and without confirmed SARS-CoV-2 infection were removed from refrigerated storage within 7 days of collection. All patients included in this study were tested for SARS-CoV-2	Patient selection: 215 specimens were collected from 155 unique patients with a documented negative SARS-CoV-2 molecular diagnostic result generated on the same day or 1 day prior to serum or plasma specimen collection. Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: patients tested positive for SARS-CoV-2 infection by PCR

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		infection with one of 3 molecular diagnostic methods Age: NR Gender (%female): NR Collection start date: Collection end date:			
43.	Author, year: Huber 2021[43] Country: Germany Study Design: Case Control	Total Number of patients: 572 Patient selection: A total of 345 serum or plasma samples from 207 patients with PCR-proven COVID-19 were tested Age: NR Gender (%female): NR Collection start date: 5/1/2020 Collection end date: 12/1/2020	Patient selection: 80 controls from the pre-COVID-19 era Age: NR Gender (%female): NR	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: patients with PCR-confirmed COVID-19 disease (COVID-19 group)
44.	Author, year: Huyghe 2020[44] Country: Belgium Study Design: Case Control	Patient selection: samples used for evaluation of sensitivity (n=186) were collected during the COVID-19 outbreak (March–April 2020) from 84 symptomatic patients Age: mean 64 Gender (%female): 35% Collection start date: 3/1/2020 Collection end date: 4/1/2020	Patient selection: Samples (n=120) used in the experiments for specificity were collected before September 2019. Age: NR Gender (%female): NR	Test name: DiaSorin Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: positive COVID-19 SARS-CoV-2 PCR result on a respiratory sample

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45.	<p>Author, year: Igawa 2021[45]</p> <p>Country: Japan</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 177</p> <p>Patient selection: Two hundred and thirty-six (236) serum samples were collected from a total of 79 symptomatic COVID-19 patients between March and August 2020.</p> <p>Age: Mean: 51 years</p> <p>Gender (%female): 30.40%</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 8/1/2020</p>	<p>Patient selection: Specificity of the antibody assay was assessed using the pre-COVID-19 samples. Two out of 98 samples were detected as positive by CV2T</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: Siemens CV2G</p> <p>Platform: CLIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p> <p>Test name 2: Siemens COV2T</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: RT-PCR was considered the gold standard for the detection of SARS-CoV-2</p>
46.	<p>Author, year: Imai 2020[46]</p> <p>Country: Japan</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 160</p> <p>Patient selection: We examined 139 serum specimens collected from 112 patients with COVID-19</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 2/11/2020</p> <p>Collection end date: 3/31/2020</p>	<p>Patient selection: 48 serum specimens collected from 48 non-COVID-19 patients.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Artron</p> <p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: All patients were examined by RT-qPCR for SARS-CoV2 using pharyngeal and nasopharyngeal swabs collected at public health institutes or hospitals in accordance with the nationally recommended method in Japan</p>

47.	<p>Author, year: Infantino 2020[47]</p> <p>Country: Italy</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 105</p> <p>Patient selection: 61 patients hospitalized in San Giovanni di Dio Hospital (Florence, Italy) for COVID-19</p> <p>Age: 59 ± 23 years</p> <p>Gender (%female): 57%</p>	<p>Patient selection: pre COVID19 (2018-2019) disease control group of 44 patients (49 ± 17 years; 35 women and 9 men) who had rheumatic diseases (n = 31) and infectious diseases (n = 13).</p> <p>Age: 49 ± 17 years</p> <p>Gender (%female): 79%</p>	<p>Test name: SHENZHEN YHLO</p> <p>Platform: CLIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: All COVID-19 patients were confirmed to be infected with SARS-CoV-2 detected in oropharyngeal and nasopharyngeal swabs by use of RT-PCR (confirmed by two SARS-CoV-2 nucleic acid tests).</p>
48.	<p>Author, year: Interiano 2021[48]</p> <p>Country: USA</p> <p>Study Design: Cohort</p>	<p>Total Number of patients: 185</p> <p>Patient selection: collected from patients who had a positive NAAT result for SARS-CoV-2. For this group, date of symptom onset was derived from information from the medical record.</p> <p>Age: Median Age 14 Y Age Range 12 D to 19 Y</p> <p>Gender (%female): 41%</p> <p>Collection start date: 4/6/2020</p> <p>Collection end date: 10/5/2020</p>	<p>Patient selection: 78 samples that were collected prior to the COVID-19 era (before February of 2020) from pediatric patients at our institution</p> <p>Age: median age:12.5 years old, ranging from 11 days to 19 years old.</p> <p>Gender (%female): 56%</p>	<p>Test name 1: Abbott CoV-2 IgM (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: samples was collected from patients who had a positive NAAT result for SARS-CoV-2</p>
49.	<p>Author, year: Jacot 2021[49]</p>	<p>Total Number of patients: 400</p>	<p>Patient selection: SARS-CoV-2 negative sera were collected</p>	<p>Test name 1: NovaTec NovaLisa</p>	<p>Reference: gold standard RT-PCR</p>

	<p>Country: Switzerland</p> <p>Study Design: Case Control</p>	<p>Patient selection: The pool of sera used in this evaluation was selected from the sera collection used in our previous study [25]. All sera were collected at the Lausanne University Hospital (CHUV), Switzerland. A pool of 180 sera (97 positive and 83 negative) were used during the preliminary phase of the evaluation (Tables 1 and S1). An extended evaluation phase was completed on additional samples to analyze the different tests on a complete total panel for the two phases of 400 sera (100 positive and 300 negative).</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>before November 1, 2019, assumed to be prior to the SARS-CoV-2 pandemic. Possible cross-reactivity was assessed through testing of sera known to be positive for other microorganisms or auto-immune disease (lupus).</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	
50.	<p>Author, year: Jugwanth 2022[50]</p> <p>Country: South Africa</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 530</p> <p>Patient selection: Participants who tested positive (n = 391) by Quantitative reverse transcription PCR (RT-qPCR) were used as positive controls.</p> <p>Age: median 41</p> <p>Gender (%female): 57%</p>	<p>Patient selection: Negative controls were identified for testing from 4 different sources (n = 139): 1. Well-characterised stored serum samples which were stored in a biorepository prior to February 2020 2. Contacts of infected patients who tested negative by RT-qPCR on two</p> <p>Age: median 43</p> <p>Gender (%female): 57%</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: The cumulative sensitivity of both assays was compared to RT-qPCR</p>

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51.	<p>Author, year: Jung 2020[51]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 161</p> <p>Patient selection: 104 patient samples that were RT-PCR positive for SARS CoV-2</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: Analytical specificity was assessed by testing 19 different patient samples known to be positive for other viruses by molecular testing (including Influenza A, Influenza B, respiratory syncytial virus (RSV), adenovirus, rhinovirus)</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Ansh Laboratories</p> <p>Platform: ELISA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: 104 patient samples that were RT-PCR positive for SARS CoV-2</p>
52.	<p>Author, year: Kim 2022[52]</p> <p>Country: Korea</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 60</p> <p>Patient selection: Between February 28th and May 6th, 2020, nasopharynx swabs, oropharyngeal swabs, and sputum were collected from 30 patients infected with SARS-CoV-2</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 2/26/2020</p> <p>Collection end date: 5/6/2020</p>	<p>Patient selection: 30 healthy volunteers</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: RapiGen Biocredit</p> <p>Platform: LFIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference:</p>
53.	<p>Author, year: Kittel 2021[53]</p>	<p>Total Number of patients: 991</p>	<p>Patient selection: (2) pre-pandemic sera (n = 97); and</p>	<p>Test name: Euroimmun</p>	<p>Reference: Serum specimens from qRT-</p>

	Country: Germany Study Design: Case Control	Patient selection: COVID-19 cases confirmed by qRT-PCR (n = 183) Age: NR Gender (%female): NR	(2A) probably COVID-19-negative sera with negative serological results from at least two or more different assays (n = 152) Age: NR Gender (%female): NR	Platform: ELISA EUA certified: Yes CE certified: Yes	PCR-confirmed patients (Class 1) were analysed.
54.	Author, year: Kohmer 2020[54] Country: Germany Study Design: Case Control	Total Number of patients: 58 Patient selection: We collected follow up serum or plasma samples (in the following simply stated as samples) from individuals with PCR-diagnosed infections with SARS-CoV-2 (n = 45) Age: NR Gender (%female): NR	Patient selection: follow up samples of recent PCR-diagnosed infections with SARS-CoV (2 patients from the 2003 outbreak), HCoV-OC43 (n = 2), HCoV-HKU1 (n = 1), HCoV-NL63 (n = 1), HCoV-229E (n = 2), recent serological/PCR-diagnosed infections with acute EBV (n = 5) Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: Collected follow up serum or plasma samples (in the following simply stated as samples) from individuals with PCR-diagnosed infections with SARS-CoV-2
55.	Author, year: Kubota 2021[55] Country: Japan	Total Number of patients: 402 Patient selection: This study involved 33 Japanese patients with laboratory-confirmed COVID-19 who were referred to Saitama Medical University Hospital in	Patient selection: 110 residual serum samples randomly recruited under a previous research protocol as negative controls from Japanese patients admitted to Saitama	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes	Reference: All patients were confirmed to have COVID-19 by RT-PCR for SARS-CoV-2 using nasopharyngeal swab specimens in

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	Study Design: Case Control	<p>Japan from February 11 to December 31, 2020.</p> <p>Age: Median age: 67 years</p> <p>Gender (%female): 33.30%</p> <p>Collection start date: 2/11/2020</p> <p>Collection end date: 12/31/2022</p>	<p>Medical University Hospital from April to October 2019 were used as negative controls.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>CE certified: Yes</p>	<p>accordance with the nationally recommended protocol in Japan</p>
56.	<p>Author, year: Kulkarni 2021[56]</p> <p>Country: India</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 270</p> <p>Patient selection: A total of 180 serum/plasma samples were obtained from RT-PCR confirmed COVID-19 patients or their asymptomatic contacts admitted at Bharati Hospital and Research Centre, Pune, India, following informed written consent. Blood samples from these patients were collected at different times post-disease onset (0-26 days, average: 10.4 days) and stored at -80°C till the time of testing.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: Ninety serum/plasma samples collected from healthy blood donors before the emergence of SARS-CoV-2 (during 2017-2019) were included as negative controls.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: Inbios IgM</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: PCR</p>
57.	<p>Author, year: Lin 2021[57]</p> <p>Country: Taiwan</p>	<p>Total Number of patients: 270</p> <p>Patient selection: we collected 184 residual blood samples from 70 consecutively qRT-PCR-confirmed COVID-19 patients hospitalized at four</p>	<p>Patient selection: included 200 control serum samples from 200 hospitalized patients who were tested negative ≥ 2 times</p>	<p>Test name 1: Beckman</p> <p>Platform: CLIA</p> <p>EUA certified: No</p>	<p>Reference: qRT-PCR-confirmed COVID-19 patients</p>

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	Study Design: Case Control	<p>participating hospitals from 23 January 2020 to 30 Sep 2020.</p> <p>Age: age was 42.6 years (standard deviation, 15 years).</p> <p>Gender (%female): 51.40%</p> <p>Collection start date: 1/23/2020</p> <p>Collection end date: 9/30/2020</p>	<p>using SARSCoV-2 qRT-PCR to evaluate diagnostic specificity</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>CE certified: Yes</p> <p>Test name 2: Siemens COV2T</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	
58.	<p>Author, year: Liu 2020[58]</p> <p>Country: China</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 336</p> <p>Patient selection: RT-PCR confirmed COVID19 patients admitted to the hospital. Out of the 192, 83 (43%) have severe disease (respiratory distress, hypoxia, severe complications)</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 144 Sera collected in the same period</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Wantai</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: RT-PCR confirmed COVID19 patients</p>
59.	<p>Author, year: Lokida 2022[59]</p> <p>Country: Indonesia</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 107</p> <p>Patient selection: A total of 107 serum specimens for the case group were collected from real time polymerase chain reaction (RT-PCR) confirmed COVID-19 patients from several hospitals in Banten province, Indonesia.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 52 sera from repository specimens collected <2016 during acute febrile illness requiring hospitalization (AFIRE) and SEPSIS studies (Southeast Asia Infectious Disease Clinical Research 2017; Gasem et al., 2020). Of these 52 sera, 32 convalescent specimens</p>	<p>Test name 1: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Siemens ADVIA Centaur</p> <p>Platform: CLIA</p>	<p>Reference: real time polymerase chain reaction (RT-PCR) confirmed COVID-19 patients</p>

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			Age: NR Gender (%female): NR	EUA certified: Yes CE certified: Yes	
60.	Author, year: Lou 2020[60] Country: China Study Design: Case Control	Total Number of patients: 380 Patient selection: COVID19 confirmed cases should meet the following three criteria: 1) fever and/or respiratory symptoms; 2) abnormal lung imaging findings; and 3) positive result of a quantitative nucleic acid of SARSCoV-2. All patients were admitted the hospital between Jan 19 and Feb 9 2020 Age: Median 55 (IQR 45-64) Gender (%female): 39% Collection start date: 1/19/2020 Collection end date: 2/9/2020	Patient selection: Healthy individuals enrolled from the local community during the circulation of the virus. All controls report no contact with a COVID-19 case Age: NR Gender (%female): NR	Test name: Wantai Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: PCR-confirmed
61.	Author, year: Maine 2020[61] Country: USA Study Design: Case Control	Total Number of patients: 1154 Patient selection: residual peripheral blood samples collected from patients for standard of care purposes were utilized. Specimens derived from 427 patients who tested positive for SARS-CoV-2 by RT-PCR between March and August 2020	Patient selection: specimens to assess test specificity included 427 patients who were symptomatic but PCR negative for SARS-CoV-2. Age: NA Gender (%female): NA	Test name 1: Abbott CoV-2 IgM (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: patients who tested positive for SARS-CoV-2 by RT-PCR

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		<p>Age: 0–19: 0.2 %, 20–29: 2.1 %, 30–39: 6.0 %, 40–49: 9.5 %, 50–59: 16.7 %, 60–69: 24.1 %, 70–79: 22.0 %, 80–89: 14.8 %, ≥90: 4.4 %.</p> <p>Gender (%female): NA</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 4/1/2020</p>		<p>Test name 2: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	
62.	<p>Author, year: Maine 2022[62]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 1101</p> <p>Patient selection: 1257 specimens derived from 402 patients who tested positive for SARS-CoV-2 by RT-PCR were used. 80% of these patients were admitted to Beaumont Hospital at Royal Oak between March and August 2020,</p> <p>Age: (65.3%) of patients were > 60 years old</p> <p>Gender (%female): NA</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 8/1/2020</p>	<p>Patient selection: 394 specimens from patients who were symptomatic but PCR negative for SARS-CoV-2 were utilized. Furthermore, a cohort of 305 archived samples collected pre-pandemic (between 2010 and 2015) was included to assess test specificity.</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: Abbott AdviseDx IgG (Alinity)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: tested positive for SARS-CoV-2 by RT-PCR were used</p>
63.	<p>Author, year: Mairesse 2020[63]</p> <p>Country: Belgium</p>	<p>Total Number of patients: 229</p> <p>Patient selection: 154 patients confirmed positive to SARS-CoV-2 by RT-PCR and with COVID-19 symptoms</p>	<p>Patient selection: 75 selected non-SARS-CoV-2 sera with a potential cross-reaction to the SARS-CoV-2 immunoassay.</p> <p>Age: NR</p>	<p>Test name: SHENZHEN YHLO</p> <p>Platform: CLIA</p> <p>EUA certified: No</p>	<p>Reference: 154 patients confirmed positive to SARS-CoV-2 by RT-PCR and with COVID-19 symptoms.</p>

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	Study Design: Case Control	Age: NR Gender (%female): NR Collection start date: 5/15/2020 Collection end date: 5/30/2020	Gender (%female): NR	CE certified: Yes	
64.	Author, year: Mallon 2021[64] Country: Ireland Study Design: Case Control	Total Number of patients: 752 Patient selection: For this analysis, we included AIID Cohort participants who presented to the Mater Misericordiae University Hospital and St Vincent's University Hospital with symptoms consistent with COVID-19 Age: 57 (45–68) Gender (%female): 46 Collection start date: 3/26/2020 Collection end date: 7/10/2020	Patient selection: Controls pre-2020 group comprised 401 subjects who provided 452 samples collected before 2020, including 116 samples taken during previous flu seasons. Age: 45 (40–53) Gender (%female): 41.60%	Test name: Abbott CoV-2 IgM (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: Sensitivity was calculated based on samples from subjects who tested detected on SARS-CoV-2 PCR (SARS-CoV-2 Pos)
65.	Author, year: Manalac 2020[65] Country: USA Study Design: Case Control	Total Number of patients: 312 Patient selection: 97 specimens from 97 patients or healthcare workers with RT-PCR confirmed and/or clinical assessment indicated SARS-CoV-2 infections Age: NR Gender (%female): NR	Patient selection: Specificity was determined by using 847 de-identified remnant serum samples from rheumatoid disease screening (n = 643; 2011–2013), therapeutic drug monitoring (TDM) of lamotrigine, levetiracetam, testing for thyroglobulin (Tg), CA125, CA19-9, CEA, and AFP	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: RT-PCR confirmed and/or clinical assessment indicated SARS-CoV-2 infections

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			Age: range 1 to 95 years Gender (%female): 67%		
66.	Author, year: Marlet 2020[66] Country: france Study Design: Case Control	Total Number of patients: 152 Patient selection: clinical performance of immunoassays were evaluated on 63 COVID-19 patients tested positive for SARS-CoV-2 RNA by RT-PCR at Tours University Hospital Age: 79/67–90 Gender (%female): 60.30% Collection start date: 4/8/2020 Collection end date: 5/11/2020	Patient selection: Specificity was evaluated on plasma collected before the end of 2019 in 89 patients Age: 30/11–54 Gender (%female): 54%	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: patients tested positive for SARS-CoV-2 RNA by RT-PCR
67.	Author, year: Martinaud 2020[67] Country: France Study Design: Case Control	Patient selection: clinical sensitivity was assessed using case serum obtained from COVID-19 patients (n = 101) admitted to the Military Medical Center Percy, France Age: 75+/- 13 years Gender (%female): NA	Patient selection: Clinical specificity was assessed using archived serum samples from healthy donors, obtained in March 2019 (n = 500) Age: 500 Gender (%female): NA	Test name: MosaiQ Platform: Microarray EUA certified: No CE certified: Yes	Reference: ARS-CoV-2 infection was confirmed by PCR
68.	Author, year: Meng 2020[68]	Total Number of patients: 433 Patient selection: From January 4 to April 5, 2020, data on 1876 consecutive	Patient selection: 206 non-COVID-19 patients in Wuhan	Test name: Innovita Platform: LFIA	Reference: Pharyngeal swabs were used to collect secretions from

	<p>Country: China</p> <p>Study Design: Case Control</p>	<p>patients who underwent SARS-CoV-2 nucleic acid tests and chest computed tomography were retrospectively collected in Wuhan Integrated TCM and Western Medicine Hospital. Of the 652 suspected COVID-19 patients, 237 had positive and 415 had negative SARSCoV-2 nucleic acid tests.</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 1/4/2020</p> <p>Collection end date: 4/5/2020</p>	<p>Integrated TCM and Western Medicine Hospital</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>the lateral and posterior pharyngeal walls and placed invsterile tubes (containing 1 mL sterile normal saline). Fluorescence PCR was performedvusing the SARS-CoV-2 Nucleic Acid Detection Kit.</p>
69.	<p>Author, year: Merrill 2020[69]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 209</p> <p>Patient selection: Assay sensitivity was evaluated using 54 specimens from 32 unique patients with SARS-CoV-2 infection confirmed by PCR at our institution, 35 of these 54 samples were collected within one week after a positive PCR result</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: Assay specificity was examined using two cohorts of samples: 35 specimens from patients with negative SARS-CoV-2 PCR testing and 139 specimens collected prior to December 2019 (i.e., pre-COVID). In addition, 12 of the 139 pre-COVID samples were HIV-positive</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: DiaSorin</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: positive PCR for SARS-CoV-2</p>

70.	<p>Author, year: Montesinos 2020[70]</p> <p>Country: Belgium</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 200</p> <p>Patient selection: Case serum samples (n = 128) were obtained from COVID-19 patients confirmed by RT-qPCR and CT-scans</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: Control non-SARS-CoV-2 samples (n = 72) utilised anonymous stored residual serum samples, selected as follows: 1) Sera selected from January 2018 to August 2019 (n = 62) included samples with a potential cross-reaction to the SARS-CoV-2 immunoassays, name</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: Maglumi</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: Case serum samples (n = 128) were obtained from COVID-19 patients confirmed by RT-qPCR and CT-scans.</p>
71.	<p>Author, year: Nakano 2021[71]</p> <p>Country: Japan</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 330</p> <p>Patient selection: Collected residual serum samples remaining after routine clinical testing from 105 subjects who underwent RT-PCR testing at The University of Tokyo Hospital. Of these 105 subjects, 26 were diagnosed as having COVID-19 based on the results of RT-PCR</p> <p>Age: 68.0 (24–89)</p> <p>Gender (%female): 19.20%</p>	<p>Patient selection: The RT-PCR-negative subjects had symptoms such as fever, cough or dyspnea and COVID-19 was denied by the negative results of RT-PCR. They were finally diagnosed as other diseases such as bacterial pneumonia, aspiration pneumonia, septic shock, cardiogenic shock, chronic obstructive pulmonary disease. Serum specimens were stored at – 80 °C and were centrifuged at 2300×g for 5 min before measurement.</p>	<p>Test name: SHENZHEN YHLO</p> <p>Platform: CLIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: 26 were diagnosed as having COVID-19 based on the results of RT-PCR.</p>

			Age: 67.5 (2–95) Gender (%female): 29.10%		
72.	Author, year: Narasimhan 2021[72] Country: United States Study Design: Case Control	Total Number of patients: 1236 Patient selection: For the assessment of clinical sensitivity, only inpatients with suspected SARS-CoV-2 infection with PCR and documented dates of symptom onset were included. Age: NR Gender (%female): NR	Patient selection: Specificity was evaluated in the pre-COVID-19 era remnant-banked plasma samples from 217 unique patients collected from blood donors from September to November 2019 and early COVID-19 period samples from March to April 2020. Age: NR Gender (%female): NR	Test name 1: Abbott AdviseDx IgM (Alinity) Platform: CMIA EUA certified: Yes CE certified: Yes Test name 2: Abbott AdviseDx IgG (Alinity) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: Evaluation of the IgGSP and IgMSP assays utilizing RTPCR positivity and days post-symptom onset was to confirm the infection and antibody response following the infection, respectively.
73.	Author, year: Nicholson 2021[73] Country: Australia	Total Number of patients: 459 Patient selection: Samples were obtained from the Victorian Infectious Diseases Reference Laboratory (VIDRL) at The Peter Doherty Institute for Infection and Immunity and Royal	Patient selection: Specificity was calculated using 2 groups: a population group of sera representing the Victorian population collected pre-pandemic between 2011	Test name 1: Wantai Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: SARS-CoV-2 RNA was detected in respiratory swabs by RT-PCR, and results were provided by both institutions.

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	Study Design: Case Control	Melbourne Hospital (RMH), Victoria, Australia Age: NR Gender (%female): NR	and 2018 (n = 100 to n = 312, depending on the assay tested) and a cross-reactive group representing prepandemic Age: NR Gender (%female): NR	Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	
74.	Author, year: Nilles 2021[74] Country: USA Study Design:	Total Number of patients: Patient selection: 251 SARS-CoV-2 polymerase chain reaction (PCR) positive samples from 122 patients (107 hospitalized, 15 ambulatory) treated at the Brigham and Women's Hospital (BWH) between March 30 and May 29, 2020, were selected. Age: MEDIAN: 58 (24–90) Gender (%female): 54% Collection start date: 3/30/2020 Collection end date: 4/29/2020	Patient selection: Prepandemic samples included 832 samples from the MGB Biobank collected between August 28, 2017 and September 26, 2019. Age: The median age was 44 years (range 20–89) Gender (%female): 47%	Test name 1: EDI Platform: ELISA EUA certified: Yes CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: post-PCR with reverse transcription (RT–PCR) confirmation
75.	Author, year: Nilsson 2021[75] Country: Denmark Study Design: Case Control	Total Number of patients: 257 Patient selection: 57 patients with a positive SARS-CoV-2 reverse transcription polymerase chain reaction Age: NR	Patient selection: Specificity was assessed using historical samples from 200 blood donors. Age: NR	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: The inclusion criteria were a positive SARS-CoV-2 RT-PCR test on a respiratory tract sample and the availability of a blood

		Gender (%female): NR Collection start date: 3/30/2020 Collection end date: 4/30/2020	Gender (%female): NR		sample for SARS-CoV-2 antibody testing
76.	Author, year: Ong 2020[76] Country: Netherlands Study Design: Case Control	Total Number of patients: 228 Patient selection: 117 consecutive patients were prospectively included between 6 April and 10 April Age: Median: 61 years Gender (%female): 48% Collection start date: 4/6/2020 Collection end date: 4/10/2020	Patient selection: specificity was also tested in a historical control group of randomly selected sera of 50 adult patients in September 2019 as SARS-CoV-2 was not circulating at that time Age: NR Gender (%female): NR	Test name: Healgen Platform: LFIA EUA certified: No CE certified: Yes	Reference: Samples were taken from the oral cavity and subsequently from the nasal cavity using the same nasopharyngeal swab; this was tested by NATs.
77.	Author, year: Ou 2021[77] Country: china Study Design: Case Control	Total Number of patients: Patient selection: A total of 192 patients with COVID-19 were enrolled in Guangzhou Eighth People's Hospital from January to February 2020. The diagnosis of COVID-19 was confirmed by RT-PCR assay. The disease severity varied from mild to severe. Age: NR Gender (%female): NR Collection start date: 1/1/2020	Patient selection: a cohort of 130 patients with suspected COVID-19 who had been recruited to the fever clinic or quarantine department of the hospital and finally had been excluded by the negative RT-PCR results were enrolled recruited. Age: median age (IQR): 24(21–32) years Gender (%female): 40.76%	Test name: Maglumi Platform: CLIA EUA certified: Yes CE certified: Yes	Reference: The diagnosis of COVID-19 was confirmed by RT-PCR assay.

		Collection end date: 2/1/2020			
78.	Author, year: Ozturk 2021[78] Country: Turkey Study Design: Case Control	Total Number of patients: 320 Patient selection: A total of 320 inpatient COVID-19 cases, admitted to Niğde Ömer Halisdemir University Training and Research Hospital between March 11 and June 30, 2020, were enrolled in this study. Age: mean age: 54.14 Gender (%female): 49% Collection start date: 3/11/2020 Collection end date: 6/30/2020	Patient selection: 40 serum samples were taken from patients before the COVID-19 pandemic were used as negative controls. Age: NR Gender (%female): NR	Test name: Singclean Platform: LFIA EUA certified: No CE certified: Yes	Reference: COVID-19 patients confirmed by RT-PCR and chest CT scan
79.	Author, year: Paiva 2021[79] Country: United States Study Design: Case Control	Total Number of patients: 1139 Patient selection: 71 PCR-confirmed COVID-19 Age: NR Gender (%female): 41%	Patient selection: Including 126 serum samples collected from random healthy individuals for pre-employment screening before 12 March and 937 plasma samples collected before the pandemic started in the United States (January 2020). Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CLIA EUA certified: Yes CE certified: Yes	Reference: COVID-19 patients with diagnoses confirmed by rRT-PCR on nasopharyngeal swabs

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80.	<p>Author, year: Pallett 2021[80]</p> <p>Country: UK</p> <p>Study Design: Cohort</p>	<p>Total Number of patients: 200</p> <p>Patient selection: 200 patients were evaluated using the COVID-19 IgG/IgM Rapid Test Cassettes (OrientGene). Patient history from both the Emergency Department assessment and the admission clerking were carefully evaluated</p> <p>Age: mean age 61 years, range 32–93 years</p> <p>Gender (%female): 43%</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 4/1/2020</p>	<p>Patient selection: An additional 50 patients were selected with a presumed negative diagnosis with a negative SARS-CoV-2 PCR result, admitted with an acute surgical complication or had a fever with an alternative, non-respiratory primary diagnosis.</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: Healgen</p> <p>Platform: LFIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: testing based on real-time PCR detection of SARS-CoV-2 (AusDiagnostics, Australia)</p>
81.	<p>Author, year: Pecoraro 2021[81]</p> <p>Country: Italy</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 309</p> <p>Patient selection: RT-PCR detection of SARS-CoV-2 RNA identified 75 participants (28.9%; 70 patients and 5 health care workers) with positive swab results.</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 3/31/2020</p>	<p>Patient selection: sera from 50 patients admitted to hospital, prior to the SARS-CoV-2 transmission in Italy</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: PRIMA</p> <p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: In order to diagnose the SARS-CoV-2 infection on the day of admission (day 0), samples of nasopharyngeal and/or oropharyngeal swabs for real time (RT-PCR) and serum or plasma samples were obtained from hospitalized patients</p>

82.	<p>Author, year: Pegoraro 2021[82]</p> <p>Country: Italy</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 262</p> <p>Patient selection: Study population consisted of 159 patients admitted to the emergency room, medical, and intensive care units (ICUs) of the Azienda Ospedaliera Universitaria Integrata of Verona with symptoms suggestive of SARS-CoV-2 infection</p> <p>Age: Median age: 58 years</p> <p>Gender (%female): 50.10%</p>	<p>Patient selection: 67 healthy volunteers</p> <p>Age: median age: 49</p> <p>Gender (%female): 85.10%</p>	<p>Test name 1: Maglumi</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: COVID-19 confirmed cases (symptomatic patient with SARS-CoV-2 positive molecular detection)</p>
83.	<p>Author, year: Pérez-García 2020[83]</p> <p>Country: Spain</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 251</p> <p>Patient selection: 90 patients admitted to the Emergency department between March 1 and April 6, 2020, with suspicion of COVID-19. The PCR was positive for SARS-CoV-2 for all of them.</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 2/9/2020</p> <p>Collection end date: 4/6/2020</p>	<p>Patient selection: A randomly selected group of 100 patients who had a serum sample taken for other serologic studies, from September 1 to November 30, 2019 (before the first cases of COVID-19 were reported).</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: ALLTEST</p> <p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: Group 2: (patients with positive PCR for SARS-CoV-2) They were used to evaluate the sensitivity of the serological test, using PCR as a gold standard.</p>
84.	<p>Author, year: Pérez-García 2021[84]</p>	<p>Total Number of patients: 140</p>	<p>Patient selection: Negative controls 60 serum samples from a randomly selected</p>	<p>Test name: ALLTEST</p>	<p>Reference: confirmation by PCR</p>

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	<p>Country: Spain</p> <p>Study Design: Case Control</p>	<p>Patient selection: PCR positive patients 80 patients admitted to the Emergency department between March 1 and April 28, 2020, with suspicion of COVID-19 and confirmation by PCR. All of them were symptomatic, with a median time from the onset of symptoms of 15 days (Interquartile range, 8–25 days). Residual serum samples were recovered for this evaluation.</p> <p>Age: NA</p> <p>Gender (%female): NA</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 4/28/2020</p>	<p>group of patients with a sample taken for other serologic studies, from September 1 to November 30, 2019</p> <p>Age: Median 44</p> <p>Gender (%female): 53.30%</p>	<p>Platform: LFIA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	
85.	<p>Author, year: Plaga 2021[85]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 517</p> <p>Patient selection: amples consisted of 84 residual serum/plasma from 53 COVID-19-positive patients by NAAT 3–21 days postonset of symptoms (POS)</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 40 samples from NAAT-negative presurgical patients, and 393 samples collected pre-December 2019 [299 noncrossreactivity: healthy (n = 50), pregnant (n = 10), and patients with various conditions; 94 cross-reactivity: 29 known serological/autoimmune marker</p> <p>Age: NR</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: COVID-19-positive patients by NAAT</p>

			Gender (%female): NR		
86.	Author, year: Prazuck 2020[86] Country: France Study Design: Case Control	Total Number of patients: 164 Patient selection: 262 serum samples collected in the Virology Laboratory of Bichat-Claude Bernard and Saint-Louis University-Hospitals both in Paris, France Age: median 52 Gender (%female): 33.40%	Patient selection: We constituted a negative panel of 120 sera, all collected before November 2019, to assess the specificity, including samples for testing as part of routine clinical care (n = 56) and serum samples corresponding to a cross-reactivity panel (n = 64) Age: NR Gender (%female): NR	Test name: AAZ COVID-PRESTO Platform: LFIA EUA certified: No CE certified: Yes	Reference: Eighty-eight serum samples were collected from 54 patients with a confirmed COVID-19 diagnosis by a positive nasopharyngeal sample RT PCR
87.	Author, year: Puschel 2021[87] Country: Chile Study Design: Case Control	Total Number of patients: 522 Patient selection: 304 of these were symptomatic adults who consulted at these clinics between 8 April and 14 May 2020. They fulfilled the criteria defined by the World Health Organization of suspected cases or had any respiratory symptoms at the time of the visit. Age: 42.5 ± 15.3 Gender (%female): 53.6 % Collection start date: 4/8/2020	Patient selection: 218 asymptomatic individuals belonging to high-risk groups, such as close contacts of confirmed cases, primary care health personnel, or prison officers working in high-risk environments in the study area, were also invited to participate in the study Age: NR Gender (%female): NR	Test name: Acro Biotech Platform: LFIA EUA certified: No CE certified: Yes	Reference: At entry (day 1), all participants were tested for COVID-19 through a standard RT-PCR test using a nasopharyngeal swab.

		Collection end date: 5/14/2020			
88.	Author, year: Qiu 2020[88] Country: China Study Design: Case Control	Total Number of patients: 864 Patient selection: A total of 475 RT-qPCR confirmed cases of COVID-19 individuals and 389 cases of controls (non-COVID-19 patients) were enrolled from four medical institutions in Hubei Province between January 20 2020 and March 12 2020. These medical institutions included Zhongnan Hospital of Wuhan University, Wuhan Third Hospital-Tongren Hospital of Wuhan University, Huang Gang Central Hospital and Hebi City Center for Disease Control and Prevention. All cases were adult (age \geq 18) and the pregnant women were excluded in this study. Age: median (IQR) 60 (49–69) Gender (%female): 47%	Patient selection: 389 cases of controls (non-COVID-19 patients) were enrolled from four medical institutions in Hubei Province between January 20 2020 and March 12 2020. These medical institutions included Zhongnan Hospital of Wuhan University, Wuhan Third Hospital-Tongren Age: 45 (29–61) Gender (%female): 42.42%	Test name: Autobio Diagnostics Platform: CLIA EUA certified: No CE certified: Yes	Reference: RT-qPCR confirmed cases of COVID-19 individuals
89.	Author, year: Rostamzadeh 2021[89] Country: Iran Study Design: Case Control	Total Number of patients: 456 Patient selection: 111 hospitalized COVID-19 patients admitted in Dr. Shariati hospital and 34 recovered COVID-19 patients recruited to Baqiyatallah hospital included in the present study.	Patient selection: 311 prepandemic normal serum samples collected 2 years before COVID-19 pandemic Age: NR Gender (%female): NR	Test name: Pishtaz Platform: ELISA EUA certified: No CE certified: Yes	Reference: The diagnosis of COVID-19 was based on the clinical manifestations, including common symptoms and signs, chest CT scan, laboratory findings, as well as primer–probe-

		Age: The mean age of the hospitalized COVID-19 patients was 56 years Gender (%female): 42.30%			based real-time RT-PCR
90.	Author, year: Saluzzo 2021[90] Country: Study Design:	Total Number of patients: 452 Patient selection: 128 symptomatic COVID-19 patients who resulted positive with rRT-PCR performed on nasopharyngeal swab (NPS) participated in the study Age: NR Gender (%female): 32% Collection start date: 4/1/2020 Collection end date: 2/1/2021	Patient selection: To evaluate the specificity of the tests, 196 samples collected and stored before 2019 were included in the analysis; 82 were from patients in therapy for tuberculosis (TB), and 114 were from healthy donors Age: range 21-48 Gender (%female): 52.7	Test name 1: Innovita Platform: LFIA EUA certified: Yes CE certified: Yes Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: with rRT-PCR performed on nasopharyngeal swab (NPS) participated in the study
91.	Author, year: Şener 2022[91] Country: Turkey Study Design: Case Control	Total Number of patients: 193 Patient selection: Serum samples were obtained from SARS-CoV-2 infected patients admitted to three university hospitals (Hacettepe, Ankara, and Ege Universities) and Ankara Bilkent City Hospital between June 24 and November 27, 2020. The patient group consisted of 143 patients with positive RT-PCR results, classic COVID-19 symptoms, and/or chest CT findings	Patient selection: A subset of 50 serum samples that has been obtained in 2019 from anti-CMV, anti-HSV1, and anti-EBNA IgG-positive patients and stored at -80°C, were used as pre-pandemic control samples Age: NR Gender (%female): NR	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: The patient group consisted of 143 patients with positive RT-PCR results, classic COVID-19 symptoms, and/or chest CT findings

		Age: 43 years (range: 20–87 years) Gender (%female): 52% Collection start date: 6/24/2020 Collection end date: 11/7/2020			
92.	Author, year: Serrano 2020[92] Country: Spain Study Design: Case Control	Total Number of patients: 171 Patient selection: The study included 152 sera from patients of which 109 were RT-PCR positive. Age: NR Gender (%female): NR Collection start date: 3/15/2020 Collection end date: 4/23/2020	Patient selection: Specificity was calculated with 62 available serum samples from 2018/19 Age: NR Gender (%female): NR	Test name 1: ALLTEST Platform: LFIA EUA certified: Yes CE certified: Yes Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: The study included 152 sera from patients of which 109 were RT-PCR positive
93.	Author, year: Serre-Miranda 2021[93] Country: Portugal Study Design: Case Control	Total Number of patients: 125 Patient selection: This study includes 89 inpatients infected with SARS-CoV-2 (diagnosed and re-confirmed during hospitalisation by RT-qPCR) Age: Range: 30-96 years Gender (%female): 57.30%	Patient selection: 36 from healthy and HIV-infected individuals. Age: Range: 33-80 years Gender (%female): 44.40%	Test name: Innovita Platform: LFIA EUA certified: Yes CE certified: Yes	Reference: Patients living in the Minho region of Portugal who were inpatients at Senhora da Oliveira Hospital (Guimarães) or Braga Hospital, admitted with COVID-19 (diagnosed by RT-qPCR at a reference

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					laboratory; at least 2 positive RT-qPCR results were obtained.
94.	Author, year: Shen 2020[94] Country: China Study Design: Cohort	Total Number of patients: 150 Patient selection: Patients presenting to Taizhou Public Health Medical Center, Taizhou Hospital, Zhejiang province, China between January 20, 2020 to February 2, 2020. Patients meeting the suspected cases criteria: - Individual with pneumonia that had related epidemiological history. fever and/or respiratory symptoms; imaging manifestations of pneumonia; low or normal white-cell count or low lymphocyte count. Age: NR Gender (%female): 41% Collection start date: 1/20/2020 Collection end date: 2/2/2020	Patient selection: NA Age: NA Gender (%female): NA	Test name: Outdo Biotech Platform: LFIA EUA certified: No CE certified: Yes	Reference: At least two different samples were obtained from each patient
95.	Author, year: Sisay 2021[95] Country: Ethiopia	Total Number of patients: 200 Patient selection: Overall, 540 sequentially ordered clients were screened with symptoms of COVID-19 in the study period. Among these, 200	Patient selection: unclear Age: NR Gender (%female): NR	Test name: ACON Biotech Platform: LFIA EUA certified: Yes CE certified: Yes	Reference: against RT-PCR method

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	Study Design: Case Control	<p>clients who were volunteer to participate, gave written informed consent and assent for participation and having signs and symptoms of COVID-19</p> <p>Age: median 27</p> <p>Gender (%female): 40%</p> <p>Collection start date: 5/1/2020</p> <p>Collection end date: 7/1/2020</p>			
96.	<p>Author, year: Soleimani 2021[96]</p> <p>Country: Belgium</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 276</p> <p>Patient selection: symptomatic and hospitalized patients with positive RT-qPCR tests on nasopharyngeal swab samples and characteristic radiological lung patterns such as ground-glass opacity and/or bilateral involvement.</p> <p>Age: mean age: 65.2 years</p> <p>Gender (%female): 46.40%</p> <p>Collection start date: 2/25/2020</p> <p>Collection end date: 3/10/2020</p>	<p>Patient selection: One hundred samples obtained from COVID-19 negative subjects</p> <p>Age: mean age: 37.2 years</p> <p>Gender (%female): 60%</p>	<p>Test name: Maglumi</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: confirmed by using the coronavirus COVID-19 genesig Real-Time PCR assay nasopharyngeal swab</p>
97.	<p>Author, year: Stein 2021[97]</p> <p>Country: Canada</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 480</p> <p>Patient selection: All 140 specimens analyzed for sensitivity were confirmed positive for SARS-CoV-2 RNA by RT-PCR</p>	<p>Patient selection: Pre-outbreak samples utilized for specificity were collected prior to December 1, 2019 (Canada's first reported case was January 25, 2020) (maximum 240</p>	<p>Test name 1: Bio-Rad</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: All specimens analyzed for sensitivity were confirmed positive for SARS-CoV-2 RNA by RT-PCR targeting the</p>

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		targeting the nucleocapsid or envelope gene from nasopharyngeal swabs. Age: NR Gender (%female): NR	specimens). Cross-reactivity was evaluated using serum samples from patients who tested positive by PCR Age: NR Gender (%female): NR	Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes Test name 3: BTNX Platform: LFCIA EUA certified: No CE certified: Yes	nucleocapsid or envelope gene from nasopharyngeal swabs.
98.	Author, year: Suhandynata 2020[98] Country: USA Study Design: Case Control	Total Number of patients: 289 Patient selection: The SARS-CoV-2 positive patient cohort consisted of 54 patients at University of California San Diego Health (UCSD) Age: NR Gender (%female): NR Collection start date: 3/1/2020 Collection end date: 4/1/2020	Patient selection: 24 patients who tested positive for antinuclear antibodies (ANA) or anti-double stranded DNA (dsDNA), 10 HIV positive patients, 78 apparently healthy subjects (no respiratory symptoms per self-report), and 102 patient samples that had been stored frozen Age: NR Gender (%female): NR	Test name: Diazyme DZ-LITE Platform: CLIA EUA certified: Yes CE certified: Yes	Reference: confirmed COVID-19 diagnosis by a positive nasopharyngeal sample RT-PCR.
99.	Author, year: Tan 2020[99]	Total Number of patients: 336	Patient selection: negative controls (n=163) obtained pre-	Test name 1: Abbott CoV-2 IgG (ARCHITECT)	Reference: . All had a minimum of one real

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	Country: Singapore Study Design: Case Control	Patient selection: We collected a total of 336 non-duplicated residual serum samples for the study that were obtained from COVID-19 confirmed patients (n=173) Age: NA Gender (%female): NA Collection start date: 3/30/2020 Collection end date: 6/15/2020	December 2019 before the COVID-19 pandemic. Age: NA Gender (%female): NA	Platform: CMIA EUA certified: Yes CE certified: Yes Test name 2: Siemens ADVIA Centaur Platform: CLIA EUA certified: Yes CE certified: Yes	time reverse transcription polymerase chain reaction (rRT-PCR) respiratory sample positive on our Cobas 6800 SARS-CoV-2 assay (Roche Diagnostics, Switzerland)
100.	Author, year: Tan 2021[100] Country: Singapore Study Design: Case Control	Total Number of patients: 333 Patient selection: samples between March 30, 2020, to May 15, 2020, from COVID-19 patients in our institution on the basis of at least 1 positive RT-PCR respiratory sample Age: NR Gender (%female): NR Collection start date: 3/30/2020 Collection end date: 5/15/2020	Patient selection: negative controls obtained before December 2019, before the COVID-19 pandemic Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: at least 1 positive RT-PCR respiratory sample being positive on our cobas 6800 SARS-CoV-2 assay (Roche Diagnostics, Rotkruez, Switzerland)
101.	Author, year: Tang 2020[101] Country: USA	Total Number of patients: 256 Patient selection: Residual patient specimens that had been sent to the Barnes Jewish Hospital laboratory for	Patient selection: Control specimens included 80 patients who were symptomatic but PCR negative for SARS-CoV-2, 50 serum specimens collected	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA	Reference: The Quidel Lyra RT-PCR assay that detects the SARS-CoV-2 nonstructural Polyprotein (pp1ab)

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	Study Design: Case Control	physician-ordered complete blood count in EDTA Vacutainer tubes (BD) were utilized, 103 specimens from 48 patients with confirmed COVID-19 infection Age: NR Gender (%female): NR	and frozen in 2015 before the emergence of SARS-CoV-2, 5 specimens from patients with other coronaviruses confirmed by molecular test Age: NR Gender (%female): NR	EUA certified: Yes CE certified: Yes	was the primary method used (limit of detection 800 copies/mL)
102.	Author, year: Tanis 2021[102] Country: Belgium Study Design: Case Control	Total Number of patients: 185 Patient selection: Sensitivity samples (n = 147) were collected between March 7 and May 12, 2020 from patients hospitalized for severe COVID-19 who tested SARS-CoV-2 positive by real-time PCR on nasopharyngeal samples at least ten days after initiation of COVID-19 symptoms. Age: Median: 60 years Gender (%female): 36.70% Collection start date: 5/7/2020 Collection end date: 5/26/2020	Patient selection: Specificity samples (n = 38) were collected between January 1 and December 26, 2019 from 20 patients who received a quadrivalent influenza vaccine at least two weeks earlier, 11 patients clinically diagnosed with viral respiratory infection, and seven patients with primary Epstein-Barr virus infection. Age: Median: 22.5 years Gender (%female): 65.80%	Test name 1: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes Test name 2: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: Sensitivity samples (n = 147) were taken from SARS-CoV-2 real-time PCR-positive patients who developed COVID-19 symptoms
103.	Author, year: Theel 2020[103]	Total Number of patients: 205 Patient selection: Among the 56 COVID-19 RT-PCR-confirmed patients, 33 were	Patient selection: A total of 149 healthy adult donor serum samples collected in 2018, prior to the SARS-CoV-2 outbreak	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA	Reference: FDA EUA SARS-CoV-2 RT-PCR assay, performed on a

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	Country: United States Study Design: Case Control	hospitalized (inpatient group) and 23 were treated as outpatients (outpatient group). Age: range 21-90 Gender (%female): 46.40% Collection start date: 3/1/2020 Collection end date: 4/1/2020	(stored at -70°C) and 105 deidentified patient sera submitted for testing as part of routine clinical care in January and early February 2020 were evaluated Age: NR Gender (%female): NR	EUA certified: Yes CE certified: Yes	nasopharyngeal swab specimen
104.	Author, year: Therrien 2021[104] Country: Canada Study Design: Case Control	Total Number of patients: 240 Patient selection: SARS CoV-2 samples (sensitivity panel; n = 176) were collected from patients with various clinical symptoms, including 156 sera and 20 plasma samples Age: mean 61 Gender (%female): 57%	Patient selection: Specificity and cross-reactivity of the serological assays were evaluated using samples from patients with other laboratory-confirmed acute infections (n = 64) Age: NR Gender (%female): NR	Test name 1: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes Test name 2: BTNX Platform: LFCIA EUA certified: No CE certified: Yes	Reference: All 176 patients were confirmed positive for SARS CoV-2 infection by real-time reverse transcription-PCR (RT-PCR) on nasopharyngeal specimens
105.	Author, year: Traugott 2020[105] Country: Austria	Total Number of patients: 177 Patient selection: The study included serum/plasma samples from 77 symptomatic patients with acute SARS-CoV-2 infection (29 female, 48 male,	Patient selection: Serum samples from 100 individuals without SARS-CoV-2 infection	Test name 1: Wantai Platform: ELISA EUA certified: Yes	Reference: diagnosed by means of positive PCR from nasopharyngeal

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	Study Design: Case Control	<p>median age, 63 years; age range, 15–92 years; 1 sample per patient) diagnosed by means of positive PCR from nasopharyngeal swab/respiratory secretion samples</p> <p>Age: median age, 63 years; age range, 15–92 years;</p> <p>Gender (%female): 37.66%</p> <p>Collection start date: 2/27/2020</p> <p>Collection end date: 3/30/2020</p>	<p>Age: median age, 49 years; range, 2–93 years</p> <p>Gender (%female): 60.00%</p>	<p>CE certified: Yes</p> <p>Test name 2: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>swab/respiratory secretion samples.</p>
106.	<p>Author, year: Tré-Hardy 2021[106]</p> <p>Country: Belgium</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 287</p> <p>Patient selection: 48 positive patients with COVID-19, Blood samples positive for COVID-19 were collected from symptomatic patients who came to the emergency room.</p> <p>Age: Median 72</p> <p>Gender (%female): 42%</p> <p>Collection start date: 5/8/2020</p> <p>Collection end date: 6/9/2020</p>	<p>Patient selection: 79 samples were included in the specificity analysis and were collected before the COVID-19 outbreak.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: NovaTec NovaLisa</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Bio-Rad Platelia</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: Patients were considered positive according to the results of the quantitative reverse transcription-polymerase chain reaction (RT-qPCR).</p>
107.	<p>Author, year: Turbett 2020[107]</p>	<p>Total Number of patients: 1332</p>	<p>Patient selection: NR</p> <p>Age: NR</p>	<p>Test name: Abbott CoV-2 IgG</p>	<p>Reference: We assessed sensitivity using 128 serum</p>

	<p>Country: United States</p> <p>Study Design: Case Control</p>	<p>Patient selection: To evaluate serologic test sensitivity, two sets of serum samples from patients with laboratory-confirmed COVID-19 infection were assembled. The retrospective COVID-19-positive serum set (n = 101) was assembled by reviewing medical records of 177 unique patients for whom a serum procalcitonin test had been ordered during the COVID-19 pandemic.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Gender (%female): NR</p>	<p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>samples from symptomatic PCR-confirmed coronavirus disease 2019</p>
108.	<p>Author, year: Van Elslande 2020[108]</p> <p>Country: Belgium</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 197</p> <p>Patient selection: For analysis of sensitivity and dynamic trend to seropositivity, a total of 167 samples from 94 patients who presented at the University Hospitals Leuven with a clinical suspicion of COVID-19 in March and April 2020, and who were diagnosed with COVID-19. Only patients positive for SARS-CoV-2 with real-time polymerase chain reaction (RT-PCR) on nasopharyngeal swabs (UTM®, Copan, Italy) and for whom residual samples were available were included. RT-PCR was performed using an in-house method complying with the WHO guidelines</p>	<p>Patient selection: To assess specificity, we selected samples from 103 patients collected before January 2020 as negative controls. These included (a) a disease control group of 49 consecutive patients with a respiratory infection who had a PCR test for respiratory pathogen</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name 1: Euroimmun</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p> <p>Test name 2: Prima</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: For analysis of sensitivity and dynamic trend to seropositivity, a total of 167 samples from 94 patients who presented at the University Hospitals Leuven with a clinical suspicion of COVID-19 in March and April 2020, and who were diagnosed with COVID-19.</p>

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		Age: Median: 67.5 years Gender (%female): 30% Collection start date: 3/1/2020 Collection end date: 4/1/2020			
109.	Author, year: Van Elslande 2022[109] Country: Belgium Study Design: Case Control	Total Number of patients: 333 Patient selection: The long-term kinetics of anti-S and anti-N were determined in 882 residual samples from 231 adult patients who were positive for SARS-CoV-2 with RT-PCR on nasopharyngeal swabs between March 9th and June 12th 2020, before the introduction of SARS-CoV-2 vaccines. Age: Range 23-92 Gender (%female): 61% Collection start date: 3/9/2020 Collection end date: 6/12/2020	Patient selection: The specificity of the IgG anti-S assay was determined in 110 left-over samples collected before January 2020 that were previously used to evaluate the specificity of the Abbott IgG anti-N assay Age: NR Gender (%female): NR	Test name: Abbott CoV-2 IgG (ARCHITECT) Platform: CMIA EUA certified: Yes CE certified: Yes	Reference: PCR confirmed
110.	Author, year: Vauloup-Fellous 2021[110] Country: France Study Design: Case Control	Total Number of patients: 4590 Patient selection: 2594 sera collected from symptomatic patients with positive SARS-CoV-2 rRT-PCR on a respiratory sample Age: NR Gender (%female): NR	Patient selection: A total of 1996 serum samples expected to be negative for SARS-CoV-2, as collected before the COVID-19 outbreak in France, were also tested to assess specificity. This panel included 665/1996	Test name: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: Between March and May 2020, 2594 sera were collected from symptomatic adults (not immunocompromised) previously diagnosed with COVID-19 by rRT-

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		Collection start date: 3/1/2020 Collection end date: 5/1/2020	(33.3%) “potentially interfering sera” collected from patients Age: NR Gender (%female): NR		PCR on a respiratory sample
111.	Author, year: Velay 2020[111] Country: France Study Design: Case Control	Total Number of patients: 325 Patient selection: A total of 325 samples were used, including 55 serum samples from hospitalized patients (panel 1),; 143 serum samples from healthcare workers (panel 2) diagnosed with COVID-19 at Strasbourg University Hospital (Strasbourg, France), recruited in April 2020 Age: Range: 21- 93 years Gender (%female): 57.10% Collection start date: 4/1/2020 Collection end date: 5/9/2020	Patient selection: 67 serum and 60 plasma samples from negative controls Age: NR Gender (%female): NR	Test name 1: EDI Platform: ELISA EUA certified: No CE certified: Yes Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: Laboratory detection of SARS-CoV-2 was performed by RT-PCR testing of nasopharyngeal swab specimens according to current guidelines (Institut Pasteur, Paris, France; WHO technical guidance)
112.	Author, year: Wakita 2021[112] Country: Japan Study Design: Case Control	Total Number of patients: 214 Patient selection: Between March and June 2020, 114 serum samples were collected from 34 COVID-19 patients. We classified patients into two groups according to the WHO criteria: Group M that included mild and moderate cases	Patient selection: For the negative control, 100 serum samples collected from outpatients without infectious diseases between November and December 2018 were used Age: NR	Test name: Nadal Platform: LFIA EUA certified: Yes CE certified: Yes	Reference: All patients were confirmed to be positive according to PCR-based testing of SARS-CoV-2 using the Light Mix Modular SARS-CoV-2 (COVID-19) N-gene and E-gene

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		<p>and Group S that included severe and critical cases</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 6/30/2020</p>	Gender (%female): NR	<p>Test name 2: Roche Elecsys</p> <p>Platform: ECLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>assay (Roche Diagnostics, Tokyo, Japan) or the 2019 Novel Coronavirus Detection Kit (Shimadzu, Kyoto)</p>
113.	<p>Author, year: Wehrhahn 2021[113]</p> <p>Country: Australia</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 1080</p> <p>Patient selection: stored sera from confirmed patients with COVID-19 diagnosed by NAAT as defined by local guidelines and also household contacts seropositive for IgG by IFA in the absence of NAAT being performed</p> <p>Age: 50.7 range 7–85years</p> <p>Gender (%female): 48%</p>	<p>Patient selection: specificity samples made of pre-COVID 411, healthy adults 2019 57, hildren 2019 30,Cross-reactivity (pre-COVID) 235,Cross-reactivity (COVID 143,ARI; COVID-19PCR negative 118.</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: confirmed patients with COVID-19 diagnosed by NAAT as defined by local guidelines</p>
114.	<p>Author, year: Whitman 2020[114]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 239</p> <p>Patient selection: 79 SARS-CoV-2-positive individuals in the UCSF/ZSFG study ranged from 22 to >90 years of age (Table 1). The majority of SARS-CoV-2-positive individuals were Hispanic/Latinx (68%), reflecting the ZSFG patient population and demographics of the epidemic in San Francisco.19,20 Most</p>	<p>Patient selection: 108 pre-COVID-19 negative controls; and 52 recent samples from individuals who underwent respiratory viral testing but were not diagnosed with Coronavirus Disease 2019 (COVID-19)</p>	<p>Test name: EDI</p> <p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: SARS-CoV-2 RT-PCR-positive individuals</p>

		presented with cough (91%) and fever (86%). Age: Age, mean (S.D.) y 52.9 (15) Gender (%female): 32%	Age: NR Gender (%female): NR		
115.	Author, year: Wolf 2020[115] Country: Germany Study Design: Case Control	Total Number of patients: 255 Patient selection: hospitalized COVID-19 patients admitted between March 6 and May 2, 2020 to the Department of Infectious Diseases/Tropical Medicine, Nephrology and Rheumatology at Hospital St. Georg in Leipzig, Germany Age: Median: 64 years Gender (%female): 35.30% Collection start date: 3/6/2020 Collection end date: 5/2/2020	Patient selection: Controls included 57 specimens of employees of the central fire brigade in Leipzig, Germany (blood withdrawal between March 28 and April 4, 2020) who were subjected to strict hygiene measures to prevent SARS-CoV-2 spreading and without any known contact t Age: NR Gender (%female): NR	Test name 1: Virotech Platform: ELISA EUA certified: Yes CE certified: Yes Test name 2: Euroimmun Platform: ELISA EUA certified: Yes CE certified: Yes	Reference: To detect SARS-CoV-2 virus particles, either nasopharyngeal swabs (Copan Liquid Amies eSwabs, Brescia, Italy) or pharyngeal lavage specimens were analyzed by RT-PCR.
116.	Author, year: Wolff 2020[116] Country: Belgium Study Design: Case Control	Total Number of patients: 205 Patient selection: A total of 111 samples from symptomatic (n = 87) and asymptomatic (n = 24) COVID-19 patients confirmed by qRT-PCR were tested. Age: Range: 20-88 years Gender (%female): 42.30%	Patient selection: The assay specificity was assessed by testing residual serum samples non-SARS-CoV-2 (n = 96) collected before the pandemic COVID-19 from January to February 2019. Age: NR Gender (%female): NR	Test name 1: VIDAS Platform: FEIA EUA certified: Yes CE certified: Yes Test name 2: Euroimmun	Reference: A total of 111 samples from symptomatic (n = 87) and asymptomatic (n = 24) COVID-19 patients confirmed by qRT-PCR were tested.

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				Platform: ELISA EUA certified: Yes CE certified: Yes	
117.	Author, year: Yamamoto 2022[117] Country: Japan Study Design: Case Control	Total Number of patients: 154 Patient selection: The COG samples were composed of a total of 438 residual serum samples from 54 COVID-19 patients who were admitted to Kyoto University Hospital, Kyoto, Japan from April 2020 to January 2021. Age: median 69.5 Gender (%female): 24.10% Collection start date: 4/1/2020 Collection end date: 1/1/2021	Patient selection: The NCG samples included 100 of 1589 randomly selected serum samples that were derived from regional epidemiological surveillance of COVID-19 from September 2020 to October 2020 in Kyoto City, Japan. Age: media 43 Gender (%female): 41%	Test name 1: SHENZHEN YHLO Platform: CLIA EUA certified: Yes CE certified: Yes Test name 2: SuperFlex PerkinElmer Platform: CLIA EUA certified: Yes CE certified: Yes Test name 3: Roche Elecsys Platform: ECLIA EUA certified: Yes CE certified: Yes	Reference: All patients were confirmed to have COVID-19 infection by RT-PCR using saliva and/or nasopharyngeal swab samples.

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118.	<p>Author, year: Yang 2020[118]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 370</p> <p>Patient selection: We investigated 42 ED patients (120 samples by CEFA and 114 samples by MIA), in which 28 patients (106 samples by CEFA and 100 samples by MIA) were subsequently admitted</p> <p>Age: 56.5 (16.0)</p> <p>Gender (%female): 21%</p> <p>Collection start date: 3/6/2020</p> <p>Collection end date: 4/4/2020</p>	<p>Patient selection: Serum from 256 pre-COVID-19 healthy blood donors collected before 2019 were used to validate the specificity of the MIA assay</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Luminex xMAP</p> <p>Platform: FIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: determined by RT-PCR (Altona Diagnostics USA, Inc., Plain City, OH)</p>
119.	<p>Author, year: Yang 2021[119]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 319</p> <p>Patient selection: 246 samples were collected on different days from 70 patients who were diagnosed with COVID-19 by the RT-PCR test.</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Patient selection: 73 specimens for the specificity studies include 38 de-identified pre-pandemic (November 2018 - September 2019) heparin plasma specimens stored in our lab, 30 pairs of remnant heparin and EDTA plasma from randomly selected patients without COVID-19 diagnosis</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CMIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: RT-PCR testing</p>
120.	<p>Author, year: Yassine 2021[120]</p>	<p>Total Number of patients: 171</p>	<p>Patient selection: 70 samples from healthy blood donors collected before 2019 and used</p>	<p>Test name: NovaTec NovaLisa</p>	<p>Reference: The performance was assessed using</p>

	<p>Country: Qatar</p> <p>Study Design: Case Control</p>	<p>Patient selection: Serum samples were selected from 101 RT-PCR-confirmed COVID-19 patients, including: ICU-admitted patients (n = 35), hospitalized non-ICU patients (n = 45) and convalescent samples collected from COVID-19-recovered patients by the Qatar Communicable Disease Center (CDC) at HMC (n = 21)</p> <p>Age: Median: 48 years</p> <p>Gender (%female): 4.90%</p>	<p>in previous studies were utilized for the control group</p> <p>Age: Median: 36 years</p> <p>Gender (%female): 8.60%</p>	<p>Platform: ELISA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>anonymous samples collected from RT-PCR-confirmed SARS-CoV-2 patients admitted to Hamad Medical Corporation (HMC)</p>
121.	<p>Author, year: Yun 2021[121]</p> <p>Country: Korea</p> <p>Study Design: Case Control</p>	<p>Total Number of patients: 334</p> <p>Patient selection: retrieved 139 serial serum samples from 49 COVID-19 patients</p> <p>Age: NR</p> <p>Gender (%female): NR</p> <p>Collection start date: 3/1/2020</p> <p>Collection end date: 10/1/2020</p>	<p>Patient selection: We also retrieved 195 serum samples from healthy donors to assess the negative percent agreement (NPA), including 95 serum samples collected before November 2019 (in the preCOVID-19 period) and 100 serum samples from organ donors who tested negative for SARS-COV2</p> <p>Age: NR</p> <p>Gender (%female): NR</p>	<p>Test name: Abbott CoV-2 IgG (ARCHITECT)</p> <p>Platform: CLIA</p> <p>EUA certified: Yes</p> <p>CE certified: Yes</p>	<p>Reference: All diagnoses were confirmed by real-time RT-PCR</p>

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122.	<p>Author, year: Zervou 2021[122]</p> <p>Country: USA</p> <p>Study Design: Case Control</p>	<p>Patient selection: two groups of patients with PCR-confirmed COVID-19 infection, 82 inpatients and 100 outpatients.</p> <p>Age: 61 (49–74)</p> <p>Gender (%female): 39%</p> <p>Collection start date: 4/1/2020</p> <p>Collection end date: 5/1/2020</p>	<p>Patient selection: 54 serum samples that were collected before the COVID-19 pandemic or from patients testing negative for COVID-19 but confirmed with other bacterial, viral infections or autoimmune diseases.</p> <p>Age: NA</p> <p>Gender (%female): NA</p>	<p>Test name: Virotech</p> <p>Platform: ELISA</p> <p>EUA certified: No</p> <p>CE certified: Yes</p>	<p>Reference: patients with PCR-confirmed COVID-19 infection</p>
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Table s6. Narrative summaries of studies informing question around performing serology testing in people with negative NAAT

#	Study	Suspicion criteria	PCR	Serology test	PCR vs Serology
1.	Baron 2020 [123] Liechtenstein Cohort	<p>N: 221</p> <p>Inclusion: all but 94 patients diagnosed with COVID-19 in the principality of Liechtenstein during the first wave of the COVID-19 pandemic up to April 23rd, 2020 were included in this study. Diagnosis of COVID-19 was based on clinical symptoms and RT-PCR testing.</p> <p>Exclusion: non consent</p> <p>Age: median 39 years (range 3-84)</p> <p>Gender: 51.3% Female</p> <p>Disease severity: 10 patients were hospitalized to receive oxygen supply and other treatment. None of the patients needed intensive care or mechanical ventilation.</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>Timing: data presented as days since onset of symptoms</p> <p>1. Roche COBAS 6800</p> <p>2. Becton BD Max</p> <p>3. Axon Lab Cepheid GenXpert</p> <p>- Platform: PCR</p> <p>- Gene target: NR</p> <p>- Approval: NR</p> <p>- Samples: nasopharyngeal swabs</p>	<p>Timing: data presented as days since onset of symptoms</p> <p>Euroimmun</p> <p>- Platform: ELISA</p> <p>- Antibody type: IgG</p> <p>- Antibodies target: Spike S1</p> <p>- Approval: EUA, CE</p>	<p>N:221</p> <p><20 days</p> <p>PCR (-), IgG (+): 12/66 (18.18%)</p> <p>51 days</p> <p>PCR (-), IgG (+): 16/155 (10.32%)</p>
2.	Buchholtz 2021[8] Germany Case-Control	<p>N: 256</p> <p>Inclusion: Confirmed cases (26); all cases admitted at LMU Munich and PCR (+)</p> <p>Inclusion: Probable cases: 256; patients admitted to the hospital of LMU Munich with possible symptoms of SARS-CoV-2 but PCR (-)</p> <p>Exclusion: NR</p> <p>Age: median 27 y.o.</p>	<p>Timing: serum samples were collected up to 64 days from the start of the symptoms</p> <p>1. NR</p> <p>- Platform: PCR</p> <p>- Gene target: NR</p> <p>- Approval: NR</p>	<p>Timing: serum samples were collected up to 64 days from the start of the symptoms</p> <p>1. Euroimmun IgG</p> <p>- Platform: ELISA</p> <p>- Antibody type: IgG</p> <p>- Antibodies target: Spike + Nucleocapsid</p> <p>- Approval: CE,EUA</p>	<p>N:256</p> <p>1. Euroimmun IgG Anti- spike</p> <p>-PCR (-), IgG (+): 1/256 (0.39%)</p> <p>Anti-nucleocapsid</p> <p>-PCR (-), IgG (+): 4/256 (1.56%)</p>

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		Gender: 62.1% female Disease severity: NR Asymptomatic: NR Previous COVID19 infection: NR Previous COVID19 Vaccination: No	- Sample: NR	2. Wondfo COVID-19 Test for total antibodies. - Platform: LFA - Antibody type: total AB - Antibodies target: NR - Approval: CE	2. Wondfo COVID-19 Test for total antibodies. -PCR (-),total Ab (+): 0/256 (0%)
3.	Chamkhi 2022[14] Tunisia Case-Control	N: 443 Inclusion: The Inclusion criteria included 1. Age ≥18 years 2. Patients with any of the following respiratory symptoms: cough, polypnea, dyspnea, and hypoxia.3. Positive result for RT-PCR and/or abnormal lung CT scan findings Exclusion: Negative RT-PCR and chest CT without COVID-19 suspicious findings. Age: 60.59 ± 16.29 Gender: 56.43% male Disease severity: Moderate CoViD-19: 246 (55.5%) Critical CoViD-19: 197 (44.5%) (COVID-19 was considered critical if any of the following findings occurred: Oxygen saturation ≤92% or acute respiratory distress needing mechanical ventilation Shock Multiorgan failure requiring hospitalization in ICU) Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No	Timing: collected between March 2020 and April 2021 1. PCR kit (Not reported) - Platform: NR - Gene target: NR - Approval: NR - Sample: nasopharynx	Timing: collected between March 2020 and April 2021, Median time to the first serology sampling post-symptoms onset was 8 [6–12.75] days. 1. Roche Elecsys Anti-SARS-CoV-2 - Platform: CLIA - Antibody type: Total AB - Antibodies target: RBD and N protein - Approval: CE,EUA 2. Vidas SARS-COV-2 - Platform: LFA - Antibody type: IgG, IgM - Antibodies target: S protein - Approval: CE 3. Abbott SARS-CoV-2 IgG - Platform: CMIA - Antibody type: IgG - Antibodies target: N protein - Approval: CE, EUA 4. Beckman Access SARS-CoV-2 IgG	N: 443 1. Roche Elecsys Anti-SARS-CoV-2 Anti-N protein PCR (-), Total AB (+): 22/80 (27.5%) Anti-RBD PCR (-), Total AB (+): 3/5 (60%) 2. Vidas SARS-COV-2 PCR (-), IgM (+): 15/33 (45.45%) PCR (-), IgG (+): 11/34 (32.35%) 3. Abbott SARS-CoV-2 IgG PCR (-), IgG (+): 2/3 (66.6%) 4. Beckman Access SARS-CoV-2 IgG PCR (-), IgG (+): 5/13 (38.64%) 5. Biosensor Standard F COVID-19 IgM/IgG PCR (-), IgM (+): 1/6(16.66%) PCR (-), IgG (+): 2/6 (33.33%)

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				<ul style="list-style-type: none"> - Platform: CLIA - Antibody type: IgG - Antibodies target: RBD - Approval: EUA <p>5. Biosensor Standard F COVID-19 IgM/IgG</p> <ul style="list-style-type: none"> - Platform: FIA - Antibody type: IgG, IgM - Antibodies target: N protein - Approval: CE 	
4.	<p>Charpentier 2021[124]</p> <p>France</p> <p>Case-Control</p>	<p>N: 35</p> <p>Inclusion: HCW who experienced symptoms suggestive of COVID-19, for whom infection was: (i) either not documented (PCR test not performed) or (ii) cleared (PCR test negative)</p> <p>Exclusion: NR</p> <p>Age: median 43 years [IQR] = 32–52</p> <p>Gender: 76.3% female</p> <p>Disease severity: NR</p> <p>Asymptomatic: No Asymptomatic patients were included in this study</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>Timing: between February 1 and March 30 2020 with a median duration between symptoms onset and PCR sampling of 5 days (IQR = 2–19).</p> <p>1. PCR test (not specified)</p> <ul style="list-style-type: none"> - Platform: NR - Gene target: NR - Approval: NR 	<p>Timing: between February 1 and March 30 2020 with a median duration between symptoms onset and serology sampling of 68 days (IQR = 56–78).</p> <p>1. COVID-Presto® test rapid Covid-19 IgG/IgM</p> <ul style="list-style-type: none"> - Platform: LFA - Antibody type: IgM, IgG - Antibodies target: NR - Approval: CE 	<p>Overall: (N: 35)</p> <p>PCR (-) IgM (+): 1/35 (2.86 %)</p> <p>PCR (-) IgG (+): 4/35 (11.43%)</p>
5.	<p>Chen 2021[125]</p> <p>China</p> <p>Case-Control</p>	<p>N: 34</p> <p>Inclusion: All subjects had clinical symptoms and CT test results in line with the national diagnosis and</p>	<p>Timing: from January 21 to March 13th 2020.</p> <p>1. ABI ViiA7 real-time fluorescent</p>	<p>Timing: from January 21 to March 13th 2020.</p> <p>1. IFlash3000</p> <ul style="list-style-type: none"> - Platform: CLIA - Antibody type: IgM, IgG - Antibodies target: Spike + 	<p>N: 34</p> <p>PCR (-), IgM (+): 29/34 (85.2%)</p> <p>PCR (-), IgG (+): 31/34 (91.1%)</p>

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		<p>treatment recommendations of COVID-19, 5th edition, but were PCR negative.</p> <p>Exclusion: NR</p> <p>Age: from 22 to 98 years</p> <p>Gender: 43.87% male</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>quantitative PCR system</p> <ul style="list-style-type: none"> - Platform: NR - Gene target: ORF1ab, N gene. - Approval: NR - Samples: NR 	<p>Nucleocapsid</p> <ul style="list-style-type: none"> - Approval: CE 	
6.	Cross 2022 [126] Singapore Cohort	<p>N: 51</p> <p>Inclusion: Patients aged 21 and above who were admitted to National University Hospital, Singapore, and had at least one nasopharyngeal PCR-negative swab at the entry to the study were recruited</p> <p>Exclusion: patients who fulfilled the MOH's case definition of a suspect case for COVID-19 were excluded from the study</p> <p>Age: median 54 (21–84)</p> <p>Gender: 62.7% male</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>Timing: between March 16, 2020, and June 19, 2020</p> <p>cobas® SARS-CoV-2 Qualitative Assay</p> <ul style="list-style-type: none"> - Platform: PCR - Gene target: ORF1ab - Approval: NR - Samples: nasopharyngeal swabs 	<p>Timing: between 3 and 12 weeks after the initial PCR test</p> <p>1.GenScript cPass SARS-CoV-2</p> <ul style="list-style-type: none"> - Platform: ELISA - Antibody type: Total Ab - Antibodies target: Spike - Approval: CE, EUA <p>2.Roche Elecsys® Anti-SARS-CoV-2</p> <ul style="list-style-type: none"> - Platform: CLIA - Antibody type: Total Ab - Antibodies target: Nucleocapsid - Approval: CE,EUA 	<p>N:51</p> <p>PCR (-), Total Ab (+): 0/51 (0%)</p>
7.	De Almeida 2021 [127] Brazil Case-Control	<p>N: 119</p> <p>Inclusion: Patients admitted to the Hospital de Clínicas, Universidade Federal do Parana (HC-UFPR), Brazil, were eligible if they had tested positive for SARS-CoV-2 on RT-qPCR.</p>	<p>Timing: NR</p> <p>1. XGEN-Master COVID-19</p> <ul style="list-style-type: none"> - Platform: NR - Gene target: 	<p>Timing: between March 1 and August 7, 2020, median time after symptoms onset: 11 (7.5, 19) days.</p>	<p>N:119</p> <p>1. Camtech COVID-19 IgM/IgG Rapid Test Kit</p>

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		<p>Inclusion: Patients admitted to the Hospital de Clínicas, Universidade Federal do Parana (HC-UFPR), Brazil, were eligible if tested RT-qPCR negative for SARS-CoV-2 but fulfilled the World Health Organization (WHO) clinical diagnostic case definitions for SARS-CoV-2.</p> <p>Exclusion: NR</p> <p>Age: median :(IQR), 61.5: (47.5, 74.5)</p> <p>Gender: 50% males</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>ORF1ab and N genes</p> <p>- Approval: NR</p> <p>- Samples: oral and nasal cavity</p>	<p>1. Camtech COVID-19 IgM/IgG Rapid Test Kit</p> <p>- Platform: LFA</p> <p>- Antibody type: IgM, IgG, IgM/IgG</p> <p>- Antibodies target: NR</p> <p>- Approval: CE</p> <p>2. Wondfo COVID-19 Test for total antibodies.</p> <p>- Platform: LFA</p> <p>- Antibody type: total AB</p> <p>- Antibodies target: NR</p> <p>- Approval: CE</p>	<p>-PCR (-), IgM (+): 6/12 (50%)</p> <p>-PCR (-), IgG (+): 2/9 (22.2%)</p> <p>-PCR (-), IgM/IgG (+): 7/12 (58.3%)</p> <p>2. Wondfo COVID-19 Test for total antibodies.</p> <p>-PCR (-),total Ab (+): 2/12 (16.67%)</p>
8.	Mirijello 2021[128] Italy Cohort	<p>N: 63</p> <p>Inclusion: age ≥ 18 years old and admission to the COVID Unit, as well as multiple negative RT-PCR and treated according to the COVID-19 protocol or deceased during hospitalization.</p> <p>Exclusion: consent denial</p> <p>Age:NR</p> <p>Gender: NR</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: NR</p> <p>Previous COVID19 Vaccination: No</p>	<p>Timing: from March to April 2020, serum sample was collected after at least 15 days from admission, or at follow-up.</p> <p>PCR analysis (NR)</p> <p>- Platform: NR</p> <p>- Gene target: NR</p> <p>- Approval: NR</p> <p>- Sample: NR</p>	<p>Timing: from March to April 2020, serum sample was collected after at least 15 days from admission, or at follow-up</p> <p>Technogenetics Sars-Cov-2 serology</p> <p>- Platform: LFA</p> <p>- Antibody type: IgM, IgG</p> <p>- Antibodies target: Nucleocapsid</p> <p>- Approval: CE</p>	<p>N: 63</p> <p>PCR (-), IgG/IgM (+): 26/63(41.3%)</p>
9.	Nakagama 2021[129] Japan	<p>N: 149</p> <p>Inclusion: HCWs at St. Marianna University School of Medicine, Yokohama City Seibu Hospital (Kanagawa, Japan) who gave consent to participate</p>	<p>Timing: Sera were obtained from the entire cohort within 3 consecutive days,</p>	<p>Timing: Sera were obtained from the entire cohort within 3 consecutive days, from 30 June to 2 July 2020.</p>	<p>N:149</p> <p>PCR (-), IgG (+): 23/149 (15.43%)</p>

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	Case-Control	<p>in the study following a covid-19 outbreak in April and May 2020 were recruited.</p> <p>Exclusion: NR</p> <p>Age: NR</p> <p>Gender: NR</p> <p>Disease severity: The majority of symptomatic COVID-19 cases were mild to moderate illnesses, and only 1.6% HCWs required O₂ supplementation</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>from 30 June to 2 July 2020.</p> <p>1. PCR test (not specified)</p> <ul style="list-style-type: none"> - Platform: NR - Gene target: nucleocapsid gene - Approval: NR - Samples: nasal swabs 	<p>1. Abbott SARS-CoV-2 IgG</p> <ul style="list-style-type: none"> - Platform: CMIA - Antibody type: IgG - Antibodies target: nucleocapsid protein -Approval: CE, EUA <p>2. Abbott SARS-CoV-2 IgG II Quant</p> <ul style="list-style-type: none"> - Platform: CMIA - Antibody type: IgG - Antibodies target: Spike protein - Approval: CE, EUA 	
10.	Ozturk 2021[78] Turkey Case-Control	<p>N: 320</p> <p>Hospitalized: All patients were inpatients from Niğde Ömer Halisdemir University Training and Research Hospital.</p> <p>Inclusion: Confirmed cases (46); all cases with PCR (+)</p> <p>Inclusion: Probable cases: 274; cases presenting with high clinical suspicion, typical CT scan findings and epidemiological factors, for COVID-19, but PCR (-)</p> <p>Exclusion: NR</p> <p>Age: 54.14 (18–90 years old)</p> <p>Gender: 50.6% male</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p>	<p>Timing: between March 11 and June 30, 2020 ,Serum samples were obtained within 0–7 days from COVID-19 patients confirmed by RT-PCR and chest CT scan.</p> <p>1. Bio-Speedy® SARS-CoV-2 double gene RT-qPCR</p> <ul style="list-style-type: none"> - Platform: PCR - Gene target: ORF1ab, N gene - Approval: NR 	<p>Timing: between March 11 and June 30, 2020 ,Serum samples were obtained within 0–7 days from COVID-19 patients confirmed by RT-PCR and chest CT scan.</p> <p>1. Singclean</p> <ul style="list-style-type: none"> - Platform: LFA - Antibody type: IgM/IgG - Antibodies target: Nucleocapsid protein - Approval: CE 	<p>N: 320</p> <p>PCR (-) IgM (+): 25/274 (9.12 %)</p> <p>PCR (-) IgG (+): 1/274(0.36%)</p> <p>PCR (-) IgM/IgG (+): 31/274 (11.31%)</p>

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		<p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>- Sample: Combined throat/nasal swabs.</p>		
11.	<p>Pan 2020[130]</p> <p>China</p> <p>Case-Control</p>	<p>N: 39</p> <p>Inclusion: Patients hospitalized at the Zhongnan hospital, between February 6 and February 21, 2020 with clinical diagnosis of COVID-19 with radiological signs of viral pneumonia and negative PCR.</p> <p>Exclusion: NR</p> <p>Age: Median 58 (20-96) years</p> <p>Gender: Males (46%)</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>Timing: data presented as days since onset of symptoms</p> <p>1. BioGerm PCR kit</p> <p>- Platform: PCR</p> <p>- Gene target: NR</p> <p>- Approval: NR</p> <p>- Sample: Throat swab</p>	<p>Timing: data presented as days since onset of symptoms</p> <p>1. Zhuhai Livzon Colloidal gold-based immunochromatographic (ICG) strip assay</p> <p>- Platform: LFA</p> <p>- Antibody type: IgM, IgG</p> <p>- Antibodies target: NR</p> <p>- Approval: CE</p>	<p>Overall N: 39</p> <p>-PCR (-), IgM (+): 9/39 (23.1%)</p> <p>-PCR (-), IgG (+): 15/39 (38.5%)</p> <p>-PCR (-), IgM or IgG (+): 17/39 (43.6%)</p> <p>At different times N: 22</p> <p>1-7 days: (N:9)</p> <p>-PCR (-), IgM (+): 2/9 (22.2%)</p> <p>-PCR (-), IgG (+): 4/9 (44.4%)</p> <p>-PCR (-), IgM or IgG (+): 4/9 (44.4%)</p> <p>8-14 days (N: 6)</p> <p>-PCR (-), IgM (+): 2/6 (33.3%)</p> <p>-PCR (-), IgG (+): 4/6 (66.7%)</p> <p>-PCR (-), IgM or IgG (+): 5/6 (83.3%)</p> <p>≥15 days (N:7)</p> <p>-PCR (-), IgM (+): 4/7 (57.1%)</p> <p>-PCR (-), IgG (+): 5/7 (71.4%)</p> <p>-PCR (-), IgM or IgG (+): 5/7 (71.4%)</p>
12.	<p>Perez Garcia 2020[83]</p>	<p>N: 61</p> <p>Inclusion: Patients hospitalized for at least 5 days between February 9 and April 2, 2020, with clinical</p>	<p>Timing: data presented as days since onset of</p>	<p>Timing: data presented as days since onset of symptoms median: 17 days</p> <p>1. AllTest COV-19 IgG/IgM kit</p>	<p>Overall: (N: 61)</p> <p>PCR (-) IgM (+): 23/61 (37.7 %)</p> <p>PCR (-) IgG (+): 54/61 (88.5%)</p>

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	<p>Spain Case-Control</p>	<p>and radiological symptoms of viral pneumonia and negative PCR.</p> <p>Exclusion: NR</p> <p>Age: 67 (57–73) years</p> <p>Gender: 73.8% males</p> <p>Disease severity: Non-severe pneumonia (65.6%), severe pneumonia (32.8%), ARDS (4.9%)</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>symptoms median: 17 days</p> <ol style="list-style-type: none"> VIASURE SARS-CoV-2 Real Time PCR Detection Kit Allplex 2019-nCoV assay <p>- Platform: NR</p> <p>- Gene target: NR</p> <p>- Approval: NR</p> <p>- Sample: NR</p>	<p>- Platform: LFA</p> <p>- Antibody type: IgM, IgG</p> <p>- Antibodies target: Spike + Nucleocapsid</p> <p>- Approval: CE</p>	<p>PCR (-) IgM or IgG (+): 54/61 (88.5%)</p> <p>0-7 days (N:0)</p> <p>No patients screened at this time</p> <p>8-14 days (N:15)</p> <p>-PCR (-), IgM (+): 5/15 (33.3%)</p> <p>-PCR (-), IgG (+): 13/15 (86.7 %)</p> <p>-PCR (-), IgM or IgG (+): 13/15 (86.7%)</p> <p>15-21 days (N:31):</p> <p>-PCR (-), IgM (+): 14/31 (45.2%)</p> <p>-PCR (-), IgG (+): 30/31 (96.8 %)</p> <p>-PCR (-), IgM or IgG (+): 30/31 (96.8%)</p> <p>22–28 days (N:14):</p> <p>-PCR (-), IgM (+): 4/14 (28.6%)</p> <p>-PCR (-), IgG (+): 10/14 (71.4%)</p> <p>-PCR (-), IgM or IgG (+): 10/14 (71.4%)</p> <p>> 28 days (N:1):</p> <p>-PCR (-), IgM (+): 0/1 (0%)</p> <p>-PCR (-), IgG (+): 1/1 (100.0%)</p> <p>-PCR (-), IgM or IgG (+): 100.0 %</p>
13.	<p>Reich 2021[131] Canada Case-Control</p>	<p>N: 72</p> <p>Inclusion: patients aged ≥18 years admitted to an acute care hospital for >24 h who had NP swabs tested by PCR for SARS-CoV-2 were initially evaluated. Patients with repeat NP sampling PCR or serology performed were included in the study</p>	<p>Timing: from March 13 to April 17, 2020,</p> <ol style="list-style-type: none"> LightMix® Real-Time PCR COVID-19 assay 	<p>Timing: from March 13 to April 17, 2020, Antibody testing was performed on patients with serum collected ≥1 week and <4 months after initial PCR test or symptom onset.</p>	<p>N: 72</p> <p>-PCR (-), Total Ab (+): 0/72 (0%)</p>

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		<p>Exclusion: testing performed >40 days after symptom onset</p> <p>Age: NR</p> <p>Gender: NR</p> <p>Disease severity: NR</p> <p>Asymptomatic: NR</p> <p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>	<p>Platform: PCR</p> <ul style="list-style-type: none"> - Gene target: NR - Approval: NR - Samples: nasopharyngeal swabs <p>2. cobas® SARS-CoV-2 Qualitative Assay</p> <ul style="list-style-type: none"> - Platform: PCR - Gene target: ORF1ab - Approval: NR - Samples: nasopharyngeal swabs 	<p>1. Roche Elecsys® Anti-SARS-CoV-2</p> <ul style="list-style-type: none"> - Platform: CLIA - Antibody type: Total Ab - Antibodies target: Nucleocapsid - Approval: CE,EUA 	
14.	<p>Rostamzadeh, 2021[132]</p> <p>Iran</p> <p>Case-Control</p>	<p>N: 145</p> <p>Inclusion: Confirmed cases (111); all cases admitted in Dr. Shariati hospital with typical CT scan findings and epidemiological factors or PCR (+)</p> <p>Inclusion: recovered cases (34); all cases were recruited to Baqiyatallah hospital, 14 days past their recovery and PCR (-)</p> <p>Exclusion: NR</p> <p>Age: Mean age of 56 years</p> <p>Gender: 42.3% female</p> <p>Disease severity: NR</p>	<p>Timing: 20 January to 14 April 2020 data presented as days since onset of symptoms</p> <p>1. Pishtaz Teb</p> <ul style="list-style-type: none"> - Platform: PCR - Gene target: N gene and RdRP region - Approval: NR - Sample: nasopharynx and oropharynx 	<p>Timing: 20 January to 14 April 2020 data presented as days since onset of symptoms</p> <p>1. Pishtaz Teb</p> <ul style="list-style-type: none"> - Platform: Elisa - Antibody type: IgM, IgG, IgM/IgG - Antibodies target: Nucleocapsid protein - Approval: CE 	<p>Overall N: 39</p> <ul style="list-style-type: none"> -PCR (-), IgM (+): 14/39 (43.6%) -PCR (-), IgG (+): 16/39 (41%) -PCR (-), IgM/IgG (+): 17/39 (43.6%) <p><7 days: (N:31)</p> <ul style="list-style-type: none"> -PCR (-), IgM (+): 11/31 (35.5%) -PCR (-), IgG (+): 11/31 (35.5%) -PCR (-), IgM/IgG (+): 12/31 (38.7%) <p>> 7 days (N: 8)</p> <ul style="list-style-type: none"> -PCR (-), IgM (+): 3/8 (37.5%)

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		Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No			-PCR (-), IgG (+): 5/8 (62.5%) -PCR (-), IgM/IgG (+): 5/8 (62.5%)
15.	Sacristan 2021[133] Spain Case-Control	N: 50 Inclusion: (n=36) Confirmed cases ;Patients with SARS-CoV-2 infection between 6 March and 1 April 2020 and PCR (+) Inclusion: (n=14) clinically diagnosed patients with pneumonia, showing clinical and radiographic evidence compatible with COVID19 according to the 5th edition of guideline on diagnosis and treatment of the novel coronavirus pneumonia and PCR(-) Exclusion: NR Age: NR Gender: NR Disease severity: NR Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No	Timing: serum samples were obtained from patients between 6 March and 1 April 2020. 1. qCOVID-19 (Genomica, Madrid, Spain) 2. Allplex 2019-nCoV assay 3. CFX96™ (Bio-Rad) - Platform: PCR - Gene target: NR - Approval: NR - Sample: NR	Timing: median time between PCR and serology was 11.4 days for patients with (+) PCR and 4.9 days for patients with (-) PCR. 1. Covid-19 VIRCLIA - Platform: CMIA - Antibody type: IgG, IgM/IgG - Antibodies target: Spike + Nucleocapsid - Approval: CE 2. Abbott SARS-CoV-2 IgG assay - Platform: CMIA - Antibody type: IgG - Antibodies target: RBD - Approval: CE + EUA 3. Wondfo® SARS-CoV-2 Antibody - Platform: LFA - Antibody type: Total antibody - Antibodies target: Spike S1/S2 - Approval: CE 4. AllTest COV-19 IgG/IgM kit - Platform: LFA - Antibody type: IgM, IgG,	Overall N: 14 1. Covid-19 VIRCLIA -PCR (-), IgG (+): 7/14 (50%) -PCR (-), IgM/IgG (+): 8/14 (57.1%) 2. Abbott SARS-CoV-2 IgG assay -PCR (-), IgG (+): 7/14 (50%) 3. Wondfo® SARS-CoV-2 Antibody -PCR (-), total Ab (+): 7/14 (50%) 4. AllTest COV-19 IgG/IgM kit -PCR (-), IgM (+): 4/14 (28.6%) -PCR (-), IgG (+): 7/14 (50%) -PCR (-), IgM/IgG (+): 7/14 (50%)

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				IgM/IgG - Antibodies target: Nucleocapsid - Approval: CE	
16.	Tawiah 2021 [134] USA Case-Control	N: 305 Inclusion: Remnant specimens were collected from patients presenting to the Barnes Jewish Hospital ED between August 29, 2020 and September 19, 2020 who tested negative for SARSCOV-2 RNA by nasopharyngeal swab collected within 4 hours of presentation. Exclusion: NR Age: NR Gender: NR Disease severity: NR Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No	Timing: data presented as days since onset of symptoms 1. NR - Platform: NR - Gene target: NR - Approval: NR - Sample: nasopharyngeal swab	Timing: data presented as days since onset of symptoms 1. Abbott SARS-CoV-2 IgG - Platform: CMIA - Antibody type: IgG - Antibodies target: N protein - Approval: CE, EUA	N:30 <7 days PCR (-), IgG (+): 1/47 (2.12%) 7-13 days PCR (-), IgG (+): 1/20 (5%) >14 days PCR (-), IgG (+): 0/67 (0%)
17.	Van Praet 2021 [135] Belgium Case-Control	N: 17 Inclusion: patients admitted to the AZ Sint-Jan Brugge-Oostende, in Belgium between March 9 2020 and April 5 2020 with high clinical suspicion of moderate or severe Covid-19 with negative RT-PCR test on the first nasopharyngeal swab. Exclusion: NR Age: median age 68 years Gender: 61% male Disease severity: NR Asymptomatic: NR	Timing: data presented as days since onset of symptoms 1. laboratory-developed PCR. - Platform: NR - Gene target: <i>N</i> and <i>RdRp</i> genes. - Approval: NR - Sample: NR	Timing: data presented as days since onset of symptoms 1. Euroimmun - Platform: ELISA - Antibody type: IgG - Antibodies target: Spike S1 - Approval: EUA, CE 2. Abbott Architect - Platform: CMIA - Antibody type: IgG - Antibodies target:	N: 17 1. Euroimmun 0-14 days : -PCR (-), IgG (+): 7/17 (41.1 %) > 14 days : -PCR (-), IgG (+): 9/17 (52.9%) 2. Abbott Architect 0-14 days : -PCR (-), IgG (+): 9/17 (52.9%) > 14 days : -PCR (-), IgG (+): 9/17 (52.9%)

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		<p>Previous COVID19 infection: No</p> <p>Previous COVID19 Vaccination: No</p>		<p>Nucleocapsid - Approval: EUA, CE</p> <p>3. Novatec - Platform: ELISA - Antibody type: IgG - Antibodies target: Nucleocapsid - Approval: CE</p> <p>4. Vircell - Platform: ELISA - Antibody type: IgG - Antibodies target: Spike + Nucleocapsid - Approval: CE</p>	<p>3. Novatec 0-14 days : -PCR (-), IgG (+): 7/17 (41.1 %) > 14 days : -PCR (-), IgG (+): 9/17 (52.9%)</p> <p>4. Vircell 0-14 days : -PCR (-), IgG (+): 9/17 (52.9%) > 14 days : -PCR (-), IgG (+): 9/17 (52.9%)</p>
18.	<p>Yokoyama 2021^[136] Japan Case-Control</p>	<p>N: 79 Inclusion: Confirmed cases (26); all cases with PCR (+) Inclusion: Probable cases: 53; subjects with respiratory symptoms, a history of overseas travel, or a high-risk contact with a confirmed COVID-19 case but PCR (-) Exclusion: NR Age: NR Gender: NR Disease severity: NR</p>	<p>Timing: serum samples were collected between April 22, 2020, and June 22, 2020.</p> <p>1. NR - Platform: NR - Gene target: NR - Approval: NR</p>	<p>Timing: serum samples were collected between April 22, 2020, and June 22, 2020. The mean days (\pmS.D.) between the antibody test and the onset of the symptom or the PCR test were 11.3 (\pm6.70) or 5.67 (\pm5.67) days, respectively.</p> <p>1. YHLO SARS-CoV-2 IgM and IgG - Platform: CLIA - Antibody type: IgM, IgG. - Antibodies target: Spike +</p>	<p>N: 79 -PCR (-), IgM (+): 1/53(1.88%) -PCR (-), IgG (+): 0/53 (0%)</p>

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		Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No		Nucleocapsid - Approval: CE	
19.	Zhao 2020 ^[137] China Case-Control	N: 172 Inclusion: Patients admitted to Shenzhen Third People's Hospital between Jan 11 and Feb 9, 2020 with clinical and radiological criteria for COVID-19 and PCR confirmed at least once during hospitalization) who had negative results on repeat PCR. Exclusion: NR Age: median 48 years Gender: 51.7% females Disease severity: NR Asymptomatic: NR Previous COVID19 infection: No Previous COVID19 Vaccination: No	Timing: data presented as days since onset of symptoms 1. PCR test (not specified) - Platform: NR - Gene target: NR - Approval: NR	Timing: data presented as days since onset of symptoms 1. Wantai SARS-COV-2 Ab ELISA - Platform: Elisa - Antibody type: IgM, IgG, Total antibodies - Antibodies target: S, N protein - Approval: CE, EUA	Total: N: 173 RNA (+): 112/173 (64.7%) RNA (+) or Serology (+): 172/173 (99.4%) 1 to 7 days RNA (+): 58/87 (66.7%) RNA (+) or Serology (+): 74/94 (78.7%) 8 to 14 days RNA (+): 67/124 (54.0%) RNA (+) or Serology (+): 131/135 (97.0%) 15 to 39 days RNA (+): 25/55 (45.5%) RNA (+) or Serology (+): 90/90 (100%)

Table s7. Narrative summaries of studies informing question around performing serology testing in people with suspected MISC

Study	PIMS Suspicion Criteria	Patients Characteristics	Serology Test/ Results
Belhadjer 2020[138] France Case Series	Inclusion Criteria: Patients included are all children admitted to the hospital with signs of multisystem inflammatory state (fever, and elevated CRP) associated with acute heart failure (left ventricular systolic dysfunction), or cardiogenic shock.	N: 35 Hospitalized: Patients admitted to 12 hospitals in France and 1 hospital in Switzerland between March 22, and April 30, 2020. Age: Median 10 years Gender: 51% males Race: NR PCR testing: NP swab: 34% positive, fecal PCR:6% positive Past COVID-19 exposure: 13/35 reported a recent contact with suspected COVID-19 patients (within the past 4 months) Patients presenting symptoms: Fever (100%), GI symptoms (80%), respiratory distress (65%) rash (57%), Impaired Myocardial Function: Echocardiogram showed EF <30% (10/35), EF between 30%-50% (25/35), global left ventricular hypokinesia (31/35), coronary artery aneurysm (0/35) PICU admission: 100% (2/3 required mechanical ventilation) Laboratory results: CRP (baseline): 241 mg/mL Treatment: IVIG (25/35), IV steroids (12/35), IL-1 receptor antagonist (3/35), heparin (23/35) Outcome: 28/35 (80%) discharged	1. CIA (not specified) - Platform: CIA - Antibody type: IgG - Antibodies target: NR - Approval: NR IgM: 2/35 (5.7%) IgG: 28/35 (80%) IgA: 25/35 (71.4%)
Dufort 2020[139] USA Case Series	PIMS criteria: A confirmed case should meet clinical and laboratory criteria, and a suspected case should meet clinical and epidemiological criteria. Clinical signs: Hospitalized patient aged <21 with 1 day or more of subjective or objective fever and either one of the following signs: hypotension, shock, signs of severe cardiac illness, or signs of other	N: 99 Hospitalized: 100% Age: 0-5 years (31%), 6-12 years (42%), 13-20 years (26%) Gender: 54% male Race: Black (31/78), Asian (4/78) PCR testing: 50/98 positive	1. NR - Platform: NR - Antibody type: IgG - Antibodies target: NR - Approval: NR IgG: 76/77 (99%)

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	<p>severe end-organ damage, or at least two of the following; maculopapular rash, bilateral non-purulent conjunctivitis, signs of mucocutaneous inflammation (hands, feet, or mouth), or GI symptoms, and the absence of a more possible etiology.</p> <p>Laboratory signs: Elevated inflammatory markers (at least 2 markers elevated), and a positive COVID-19 lab test (PCR within the last 4 weeks, or Serology test anytime).</p> <p>Epidemiological criteria: Either close contact, with a confirmed or suspected COVID-19 case, and/or travel to a hotspot. Both should be within the previous 6 weeks.</p>	<p>Past COVID-19 infection: Within the past 6 weeks, 24% had viral like illness, 38% had exposure to a confirmed COVID-19 case, 22% had exposure to a suspected COVID-19 case.</p> <p>Patients presenting symptoms: Fever (100%), GI symptoms (80%), dermatologic symptoms (62%), mucocutaneous signs (61%)</p> <p>Echocardiogram: 51/93 had some degree of ventricular dysfunction, 9% showed coronary artery aneurysm.</p> <p>PICU admission: 80% admitted to the ICU, mechanical ventilation (10%).</p> <p>Laboratory results: CRP median 21.9 mg/dl, ferritin median 522 ng/mL.</p> <p>Treatment: IVIG (70%), glucocorticoids (64%), vasopressors (62%).</p> <p>Outcome: Death (2%)</p>	
<p>Feldstein, 2020[140] USA Case Series</p>	<p>PIMS criteria: Hospitalized patients (age <21), with fever, laboratory evidence of inflammation, multisystem organ involvement (at least 2 systems involved), with either positive PCR, positive serology, or history of contact with suspected or confirmed COVID-19 cases.</p>	<p>N: 186</p> <p>Hospitalized: Patients were hospitalized in 53 hospitals between March 15, 2020, to May 20, 2020.</p> <p>Age: median 8.3 years</p> <p>Gender: 62% males</p> <p>Race: 25% black, 19% white, 31% Hispanic, 5% other race, 22% unknown</p> <p>PCR testing: 73/181 (40%)</p> <p>Past COVID-19 exposure: 14 patients had symptoms of COVID-19 with median period between COVID-19 symptoms and PMIS symptoms onset was 25 days (range, 6 to 51)</p> <p>Patients presenting symptoms: Fever (100%), GI symptoms (91%), bilateral conjunctival injection (55%), oral mucosal changes (42%), peripheral extremities changes (37%), rash (59%).</p>	<p>1. NR</p> <ul style="list-style-type: none"> - Platform: NR - Antibody type: NR - Antibodies target: NR - Approval: NR <p>Positive: 85/131 (65%)</p>

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		<p>Impaired Myocardial Function:</p> <p>PICU admission: 80% admitted to PICU, 20% required mechanical ventilation,</p> <p>Laboratory results: Elevated CRP (91%), elevated ferritin (61%)</p> <p>Treatment: IVIG (77%), IV steroids (49%), IL-6 inhibitor (8%), IL-1 receptor antagonist (13%)</p> <p>Outcome: 70% discharged, 2% died, 28% still hospitalized.</p>	
<p>Grimaud, 2020^[141]</p> <p>France</p> <p>Case Series</p>	<p>PIMS criteria: This study doesn't use any PIMS or Kawasaki disease definition. It includes all patients admitted to the PICU with fever, shock, and a suspected COVID-19 infection.</p>	<p>N: 20</p> <p>Hospitalized: All patients (< 18) admitted to the PICU with shock, fever and a suspected SARS-CoV-2 infection between April 15th and April 27th, 2020.</p> <p>Age: median 10 (2.9–15)</p> <p>Gender: 50% male</p> <p>Race: NR</p> <p>PCR testing: 50% positive</p> <p>Past COVID-19 exposure: Previous viral like illness or contact with a suspected Covid-19 case wasn't reported.</p> <p>Patients presenting symptoms: None fulfilled the typical Kawasaki disease definition. However, the most common symptoms were fever (100%), severe abdominal pain (100%), vomiting (100%). Hypotensive (100%), major systematic inflammation (100%), acute myocarditis (100%) and rash (50%)</p> <p>Impaired Myocardial Function:</p> <p>PICU admission: 100%</p> <p>Laboratory results:</p> <p>Treatment: IVIG (100%), Corticosteroids (10%), IL-1 receptor antagonist (5%), anti-IL-6 monoclonal antibody (5%)</p> <p>Outcome: All patients were discharged from the PICU.</p>	<p>1. Euroimmun IgA, IgG</p> <ul style="list-style-type: none"> - Platform: Elisa - Antibody type: IgG, IgA - Antibodies target: NR - Approval: EUA <p>Serology test results: 15/20 positive for both IgA and IgG</p>

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<p>Toubiana, 2020[142] France Case Series</p>	<p>PIMS criteria: This study included all patients presenting with Kawasaki-like syndrome between 27 April and 11 May 2020</p> <p>Kawasaki Criteria: Definition based on the 2017 American Heart Association criteria for complete and incomplete Kawasaki disease.</p>	<p>N: 21</p> <p>Hospitalized: All patients presenting to the general pediatric department of Necker Hospital for Sick Children in Paris during COVID-19 pandemic.</p> <p>Age: Median: 7.9 (3.7-16.6)</p> <p>Gender: 57% females</p> <p>Race: NR</p> <p>PCR testing: 38% positive</p> <p>Past COVID-19 exposure: Patients' parents report their kids never went to school, social gatherings, or traveled since lockdown implementation. Recent viral like syndrome (headache, cough, coryza, fever for less than 48 hours) was reported in 9 patients. History of exposure to a suspected COVID-19 case (10/21)</p> <p>Duration between viral like syndrome and Kawasaki-like syndrome onset: Median: 45 (range 18-79) days</p> <p>Duration between exposure to suspected COVID-19 case and Kawasaki-like syndrome onset: Median: 36 (range 18-45) days.</p> <p>Patients presenting symptoms: Patients fulfilled complete (52%) or incomplete Kawasaki definition (48%)</p> <p>Impaired Myocardial Function: Aneurysm (0%).</p> <p>PICU admission: 81% were admitted to the PICU. Mechanical ventilation (52%), Inotropic agents (71%)</p> <p>Laboratory results: CRP 253 (89-363) mg/L.</p> <p>Treatment: IVIG (100%), steroids (48%), Aspirin (100%), antibiotics (86%)</p> <p>Outcome: all survived</p>	<p>Serology test:</p> <p>Architect SARS-CoV-2 Abbott core lab.</p> <ul style="list-style-type: none"> - Platform: CIA - Antibody type: IgG - Antibodies target: NR - Approval: EUA <p>IgG: 19/21 (90.5%)</p>
<p>Verdoni, 2020[143] Italy Case Series</p>	<p>PIMS criteria: This study included patients presenting Kawasaki-like syndrome in the Italian epicenter of COVID-19,</p> <p>Kawasaki Criteria: Definition based on the 2017 American Heart Association criteria that divides patients into two categories.</p>	<p>N: 10</p> <p>Hospitalized: Patients diagnosed with Kawasaki disease admitted to the General Paediatric Unit of Hospital Papa Giovanni XXIII (Bergamo, Italy), between Jan 1, 2015, and April 20, 2020.</p> <p>Age: Range (2-16)</p> <p>Gender: 70% boys</p> <p>Race: NR</p>	<p>1. NADAL COVID-19 IgG/IgM Test</p> <p>Platform: LFIA</p> <ul style="list-style-type: none"> - Antibody type: IgM,IgG - Antibodies target: NR - Approval: CE <p>IgM: 3/10 (30%)</p>

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	<p>Classic Kawasaki: fever for ≥ 5 days + 4 or more clinical criteria including bilateral bulbar non-exudative conjunctivitis, changes of the lips or oral cavity, non-suppurative laterocervical lymphadenopathy, polymorphic rash, erythema of the palms and soles, firm induration of the hands or feet, or both) and incomplete types.</p> <p>Incomplete Kawasaki: fever for ≥ 5 days plus + 2 or 3 of the complete Kawasaki symptoms.</p>	<p>PCR testing: 3/9 positive. (1 not done)</p> <p>Past COVID-19 exposure: 5/10 patients had contact with a suspected or confirmed COVID-19 case.</p> <p>Patients presenting symptoms: Classic Kawasaki (50%), Incomplete Kawasaki (50%)</p> <p>Impaired Myocardial Function: Abnormal echocardiography signs (60%)</p> <p>PICU admission: The number of patients admitted to the PICU was not reported, however, 2 patients required inotropes.</p> <p>Laboratory results: Elevated CRP (100%), elevated Ferritin (5/9) (55%)</p> <p>Treatment: IVIG (100%), Aspirin (20%), Methylprednisolone (80%)</p> <p>Outcome: Discharged</p>	<p>IgG: 8/10 (80%)</p> <p>IgM or IgG: 8/10 (80%)</p>
<p>Whittaker, 2020[144]</p> <p>UK</p> <p>Case Series</p>	<p>PIMS criteria: Patients meeting the UK, CDC, or WHO PIMS criteria without proof of SARS-CoV-2 exposure.</p> <p>Kawasaki Disease criteria: American Heart Association criteria; Persistent fever and 4 of 5 mucocutaneous features (erythema and cracking of lips, strawberry tongue and/or erythema of oral and pharyngeal mucosa; bilateral bulbar conjunctival injection without exudate; rash [maculopapular, diffuse erythroderma]; erythema and edema of the hands and feet in acute phase and/or periungual desquamation in subacute phase; and cervical lymphadenopathy [>1.5 cm diameter])</p>	<p>N: 58 (including 8 patients from Riphagen study)</p> <p>Hospitalized: All patients were hospitalized between 23rd March– 26thth May 2020.</p> <p>Age: Median 9 years (3 months- 17 years)</p> <p>Gender: 57% females</p> <p>Race : black (38%) or Asian (31%), White (21%), other (10%).</p> <p>PCR positive: 15 patients (26%)</p> <p>Past COVID-19 exposure : 45/58 (78%) (PCR or Serology positive)</p> <p>Patients presenting symptoms: Fever (100%), Sore throat (10%), headache (26%), abdominal pain (53%), erythematous rash (52%), conjunctival injection: (45%), lymphadenopathy (16%), mucus membrane changes and cracked lips (29%), swollen hands and feet (16%),</p> <p>Severe cases: PICU admission (50%), AKI (22%), shock requiring Inotropic support (47%), mechanical ventilation (43%):</p> <p>Laboratory results: CRP 229 (156-338) mg/L, Ferritin 610 μg/L (359-1280)</p> <p>Treatment: IVIG (71%), Corticosteroids (64%), IL-1 receptor antagonist (5%), Infliximab (14%)</p> <p>Outcome: Coronary artery aneurysm (14%), Death (2%)</p>	<p>1. EDI COVID-19 IgG ELISA Kit</p> <ul style="list-style-type: none"> - Platform: Elisa - Antibody type: IgG - Antibodies target: NR - Approval: CE <p>IgG: 40/46 (87%)</p>

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Riphagen, 2020 ^[145] UK Case Series	Study population included in Whittaker study.		
Mamishi, 2021 ^[146] Iran Cohort	MIS-C (multisystem inflammatory syndrome in children): diagnosis according to the following criteria: 1) history of close SARS-CoV-2 contact, 2) the presence of fever (> 38°C) lasting for more than 24 h, 3) signs/symptoms of at least 2 organ involvement, 4) laboratory results displaying systemic inflammation	N: 39 with MIS-C Hospitalized: All hospitalized (February 2020 – January 2021) Age: median 5 (all) Gender: NR Race: NR PCR testing: 10/39 (26%) Patients presenting symptoms: Fever, cough, tachypnea, and vomiting were listed as the most common clinical manifestations. Severe cases: NR Laboratory results: NR Treatment: NR Outcome: NR	1. ELISA - Platform: Pishtaz Teb - Antibody type: IgG, IgM - Antibodies target: Nucleocapsid - Approval: CE IgG: 8/39 (20%) IgM: 2/26 (7%)
Sweeney, 2021 ^[147] UK Case Control	PIMS (Hyper inflammatory Kawasaki-like syndrome) criteria: Patients meeting the UK, CDC, or WHO PIMS criteria without proof of SARS-CoV-2 exposure. Kawasaki Disease criteria: American Heart Association criteria; Persistent fever and 4 of 5 mucocutaneous features (erythema and cracking of lips, strawberry tongue and/or erythema of oral and pharyngeal mucosa; bilateral bulbar conjunctival injection without exudate; rash [maculopapular, diffuse erythroderma]; erythema and edema of the hands and feet in acute phase and/or periungual	N: 30 with suspected PIMS Hospitalized: Yes – all (from May 29 th , 2020) Age: mean 8 years old Gender: 46% Females Race: NR PCR testing: 1/30 positive Past COVID-19 exposure: NR Patients presenting symptoms: Fever, GI symptoms, overlapping hyperinflammation with either typical or atypical Kawasaki disease, overlapping symptoms of Hyper-inflammation and toxic shock syndrome, and rash. Vaccination status: NR	LFIA - Platform: SureScreen - Antibody type: IgM, IgG - Antibody Target: NR - Approval: CE IgM: 3/30 (10%) IgG: 11/30 (36.6%)

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	desquamation in subacute phase; and cervical lymphadenopathy [>1.5 cm diameter])	Impaired Myocardial Function: NR PICU admission: NR Laboratory results: NR Treatment: NR Outcome: NR	
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Table s8. Narrative summaries of studies informing question around performing serology testing in people with history of COVID-19 infection

#	Author, Year	Patients Characteristics	Methodology	Outcomes and Results
1.	Addetia 2020 [148] Cohort	120 individuals on a fishery vessel with an outbreak underwent predeparture serological testing, out of which 117 tested negative and 3 tested positive. Symptoms status at the time of PCR testing: Asymptomatic Vaccination Status: Unvaccinated Presence of a comparison group: Yes	After ship returned to the shore, all 120 individuals underwent RT-PCR testing Serology tests: Neutralization assays with spike pseudotyped lentiviral particles	In the seronegative individuals, 14/117 were infected (12%) In the seropositive individuals, 0/3 were infected (0%)
2.	Ali 2021 Cohort [149]	829 patients admitted to Qala Hospital, Kalar, Kurdistan region, Iraq, underwent serology testing, out of which 742 tested negative and 87 tested positive. Symptoms status at the time of testing: Mixed Symptomatic and Asymptomatic Vaccination Status: Unvaccinated Presence of a comparison group: Yes	Patients were followed up between the last week of May until the middle of October for infection with COVID-19 using PCR testing. Serology tests: SARS-CoV-2 IgG test kit (Pishtaz TebDiagnostics, Tehran, Iran) targeting the IgG antibody against the nucleocapsid (N) antigen	In the anti-nucleocapsid-seronegative individuals, 25/87 were reinfected (29%) In the anti-nucleocapsid-seropositive individuals, 1/742 were reinfected (0%)
3.	Atti 2022 [150] Case-Control	Cases: 23 individuals with reinfections by 15th July 2021 in the form of new positive PCR test at least 4 weeks after their first antibody-positive result Controls: 92 individuals with no PCR reinfection detected. Controls were matched to cases on the criteria of gender, age, geographic region and estimated time of primary infection. Symptoms status at the time of reinfection: Mixed Symptomatic and Asymptomatic Vaccination Status: Unvaccinated	Antibody levels for spike and nucleocapsid were reviewed for both cases and controls.	Anti-S levels were significantly higher in controls ($p = 0.001$) than in cases, while no significant difference was observed for anti-N ($p = 0.29$) In the conditional logistic regression model, doubling in anti-S , levels was associated with a significant reduction in odds of reinfection of 37% (OR 0.63, CI 0.47-0.85, for doubling levels); such association has not been found for

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		Presence of a comparison group: Yes		anti-N levels (OR 0.88, CI 0.73- 1.05, for doubling of levels)
4.	Hanrath 2020 [151] Cohort	11,175 health care workers (HCW) at Newcastle-upon-Tyne Hospitals (NUTH) in the United Kingdom underwent serology testing between March 10, 2020, and July 6, 2020, out of which 10,137 tested negative and 1,038 tested positive. Symptoms status at the time of testing: Mixed Symptomatic and Asymptomatic Vaccination Status: Unvaccinated Presence of a comparison group: Yes	Patients were followed up between July 7, 2020, and November 20, 2020 for infection with COVID-19 using PCR testing. Those with a positive antibody assay were considered to be at risk for infection (or reinfection) from 60 days after their first positive antibody Serology tests: SARS-CoV-2 nucleocapsid IgG on the Roche Anti-SARS-CoV-2 IgG assay.	In the anti-nucleocapsid–seronegative health care, 2,115/10,137 underwent PCR testing, and 290/2115 tested positive (13.7%) In the anti-nucleocapsid–seropositive health care, 128/1,038 underwent PCR testing, and 0/128 tested positive (0%)
5.	Hønge 2022 [152] Cohort	3,806 non-vaccinated Danish blood donors with a history of a positive PCR test were tested for SARS-CoV-2 antibodies between week 41, 2020, through week 26, 2021, out of which 3,585 tested positive and 221 tested negative. Symptoms status at the time of testing: NR Vaccination Status: Unvaccinated Presence of a comparison group: Yes	Patients were followed up between week 41, 2020, through week 26, 2021. Donors were considered re-infected if they had 2 positive PCR tests at least 3 months apart. Serology tests: Wantai SARS-CoV-2 Ab ELISA assays detecting antibodies against the receptor-binding domain of the SARS-CoV2 spike protein	Seroconversion ratio in those with history of positive PCR: 94.2% In the anti-spike–seronegative donors, the rate of reinfection was 4,332/100,000 person-years In the anti-spike–seropositive donors, the rate of reinfection was 4,40/100,000 person-years Incidence rate ratio, 0.102 ; 95% confidence interval, 0.03 to 0.44; P=0.002)

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6.	Lumley 2021 [153] Cohort	<p>12,541 health care workers (HCW) at Oxford University Hospitals in the United Kingdom underwent serology testing between March 27, 2020, and April 23, 2020, out of which 11,364 tested negative and 1,265 tested positive</p> <p>Symptoms status at the time of testing: Mixed Symptomatic and Asymptomatic</p> <p>Vaccination Status: Unvaccinated</p> <p>Presence of a comparison group: Yes</p>	<p>Patients were followed up until November 30 for infection with COVID-19 using PCR testing.</p> <p>Those with a positive antibody assay were considered to be at risk for infection (or reinfection) from 60 days after their first positive antibody</p> <p>Serology tests: spike IgG enzyme-linked immunosorbent assay (ELISA), developed by the University of Oxford, and anti-nucleocapsid IgG assay (Abbott).</p>	<p>In the anti-spike–seronegative health care, 223 had a positive PCR test (1.09 per 10,000 days at risk)</p> <p>In the anti-nucleocapsid–seronegative health care, 226 had a positive PCR test (1.10 per 10,000 days at risk)</p> <p>In the anti-spike–seropositive health care workers, 2 had a positive PCR test (0.13 per 10,000 days at risk)</p> <p>In the anti-nucleocapsid–seropositive health care workers, 2 had a positive PCR test (0.13 per 10,000 days at risk)</p> <p>Adjusted incidence rate ratio (IRR), 0.11; 95% confidence interval, 0.03 to 0.44; P=0.002)</p>
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Table s9. Narrative summaries of studies informing question around performing serology testing in people with history of COVID-19 vaccination

#	Author, Year	Patients Characteristics	Methodology	Outcomes and Results
1.	Aldridge 2022 [154] Cohort	A cohort of 9,492 participating in antibody testing who completed at-home capillary blood sampling kits sent via post on a monthly basis. Vaccination details: At least one dose of BNT162b2, ChAdOx1, mRNA-1273, or other.	Measured antibody titres targeting the spike (S) protein (anti-S) in the context of seronegativity for SARS-CoV-2 anti-Nucleocapsid (antiN) (associated with natural infection) Serology tests: Elecsys anti-S and anti-N electro-chemiluminescent immunoassays (Roche Diagnostics, Basel, Switzerland)	Association between anti-S levels and a lower risk of SARS-CoV-2 infection (Hazard Ratio 0.85; 95%CI: 0.79-0.92) <i>"We found no evidence of an interaction between anti-S levels and second dose vaccine type in our model estimating risk of infection."</i>
2.	Anand 2022 [155] Case Control	Cases: 56 individuals persons receiving dialysis at U.S. Renal Care with breakthrough infections Controls: Each breakthrough case was 5 fully vaccinated control patients by age, sex, and vaccination month and adjusted for diabetes status and region of residence. Vaccination details: fully vaccinated received 2 doses of an mRNA vaccine according to the recommended schedule or a single dose of the attenuated adenovirus vaccine History of Previous infection: None	Remainder plasma from a laboratory processing routine monthly tests was used to measure qualitative and semiquantitative antibodies to the receptor-binding domain (RBD) of SARS-CoV-2. Serology tests: Siemens total RBD Ig assay	Breakthrough infections: <i>"Low prebreakthrough index values were associated with breakthrough infection among case patients"</i>
3.	Asderakis 2022 [156] Cohort	A cohort of 920 patients on kidney transplant patients in South Wales, United Kingdom Vaccination details: at least 1 dose of severe acute respiratory syndrome coronavirus 2 vaccine History of Previous infection: None	Blood samples were collected to detect IgG antibodies to SARSCoV-2 in sera Serology tests: COVID-SeroKlir 2-step ELISA (Kantaro Biosciences, New York, NY; supplied by EKF Diagnostics, United Kingdom).	Seroconversion rate with first dose: 127/495 (26%) Seroconversion rate with second dose: 278/593 (47%) Breakthrough infections: <ul style="list-style-type: none">• In seropositive group: 5/25 (20%)• In seronegative group: 20/25 (80%)

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				Serious Breakthrough infections: <ul style="list-style-type: none"> • In seropositive group: 1/17 (6%) • In seronegative group: 16/17 (94%)
4.	Bergwerk 2021 [157] Case control	<p>Cases: 1497 fully vaccinated health care workers for whom RT-PCR data was available.</p> <p>Controls: For each breakthrough case, we matched samples that had been obtained from four or five uninfected controls according to the following variables: sex, age, the interval between the second dose of BNT162b2 vaccine and serologic testing, and immunosuppression status</p> <p>Vaccination details: two doses of BNT162b2 vaccine</p>	<p>Follow up for individuals for breakthrough infection, which was defined as the detection of SARS-CoV-2 on RT-PCR assay performed 11 or more days after receipt of a second dose of BNT162b2 if no explicit exposure or symptoms had been reported during the first 6 days.</p> <p>Serology tests: S1 IgG antibodies (Beckman Coulter), SARS-CoV-2 pseudovirus neutralization assay, and Elecsys Anti-SARS-CoV-2 Immunoassay (Roche) to test for anti-N antigen</p>	<p><i>"Neutralizing antibody titers in case patients during the peri-infection period were lower than those in matched uninfected controls (case-to-control ratio, 0.361; 95% confidence interval, 0.165 to 0.787)."</i></p>
5.	Cromer, 2021 [158] Systematic review and meta-analysis	<p>Vaccination details: Multiple</p>	<p>24 identified studies on in-vitro neutralisation and clinical protection to understand the loss of neutralisation to existing SARS-CoV-2 variants of concern.</p>	<p><i>"Despite the variability in study design, we found that predicted serological neutralisation activity against each variant elicited by vaccines was significantly correlated with protection from symptomatic SARS-CoV-2 infection"</i></p>
6.	Gilbert, 2021 [159] Clinical trial	<p>A cohort of 1,010 who received two doses of vaccine were compared to individuals receiving placebo.</p> <p>Vaccination details: mRNA-1273</p> <p>History of Previous infection: None</p>	<p>Individuals were followed up on day 1, day 29, and day 57 and were tested for antibody results. Following day 57, they were followed up for 100 days to assess for occurrence of COVID-19 infection</p>	<p><i>"COVID-19 risk of vaccine recipients decreases as antibody marker levels increase"</i></p> <p><i>"Multiplicity-adjusted P values indicated significant inverse correlations with risk, with estimated hazard ratios for upper</i></p>

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				<i>versus lower tertiles ranging between 0.20 and 0.31"</i>
7.	McGee 2022 [160] Cohort	<p>A cohort of 521 vaccinated participants were recruited from the general population using print materials, newsletters, electronic materials, newspaper advertisements, a study-specific website, and social media postings. Recruitment began in August 2020 and continued until April 2022.</p> <p>Vaccination details: Pfizer: BNT162b2 vaccine (Pfizer-BioNTech); Moderna: mRNA-1273 vaccine (Moderna); Johnson and Johnson (Janssen): Ad26.COV2.S vaccine (Johnson&Johnson/Janssen)</p> <p>History of Previous infection: Mixed</p>	<p>Antibody responses in the sera of vaccinated patients evaluated whether there is a threshold of antibody titers associated with breakthrough infections</p> <p>Serology tests: AdviseDx SARS-CoV-2 IgG II assay (CMIA, Abbott)</p>	<p>Breakthrough infections:</p> <p><i>"There was a clear association of breakthrough cases with lower anti-spike antibody titers. This association is also demonstrated by the decreasing trend in the proportion of breakthrough cases as the anti-spike levels increased"</i></p>
8.	Murt 2022 [161] Cohort	<p>A cohort of 85 patients on hemodialysis followed up by two tertiary healthcare centers in Istanbul. They were 59.8 ± 4.2 years old, and they were on maintenance hemodialysis for 33.2 ± 39.3 months</p> <p>Vaccination details: 50 individuals received CoronaVac, an inactivated SARSCoV-2 vaccine, which was developed by Sinovac Life Sciences (Beijing, China) and 35 received BNT162b2, a nucleoside modified RNA (mRNA) vaccine developed by BioNTech Pfizer</p> <p>History of Previous infection: None</p>	<p>Antibody responses in the sera of vaccinated patients and controls were analyzed 21–28 days after the second dose of the vaccines</p> <p>Serology tests: Abbott SARSCoV-2 IgG II Quant (Chicago, USA) via Abbott ARCHITECT i1000 (Chicago, USA)</p>	<p>Seroconversion rate: 40/50 (80%) with CoronaVac</p> <p>Seroconversion rate: 34/35 (97%) with BNT162b2</p> <p>Breakthrough infections after 3 months of F/U:</p> <ul style="list-style-type: none"> • In seropositive group: 0/74 (0%) • In seronegative group: 1/11 (90%)
9.	Ollila 2022 [162] Cohort	<p>A cohort of 378 patients with any type of lymphoid, myeloid, or plasma cell malignancy at Rhode Island Hospital up till February 28, 2022</p> <p>Vaccination details: initial and booster vaccination with one of three US Food and Drug Administration-authorized or approved COVID-19 vaccines between February 2021 and February 2022</p>	<p>Blood samples were collected to detect IgG antibodies to SARSCoV-2 in sera</p> <p>Serology tests: Abbott AdviseDx SARS-CoV-2 IgG II</p>	<p>Seroconversion rate with initial vaccination: 181/378 (48%)</p> <p>Seroconversion rate with booster vaccination: 48/85 (56%)</p> <p>Breakthrough infections:</p> <ul style="list-style-type: none"> • 33/378 (9%) <p><i>"There was no evident association between seroconversion (after</i></p>

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		History of Previous infection: None		<i>either primary vaccination or booster vaccination) and the cumulative incidence of any COVID-19 infection (including asymptomatic infections"</i>
10.	Patnaik 2022 [163] Cohort	<p>A cohort of 80 patients on hemodialysis presenting to the nephrology department of Kalinga Institute of Medical Sciences. The patients included 61 (76.25%) males with a mean age of 46±13.57 years.</p> <p>Vaccination details: two doses of either COVID-19 vaccine (BBV152 or AZD1222). The time interval between two doses of vaccine was four to six weeks for BBV152 and 12 to 16 weeks for AZD1222</p> <p>History of Previous infection: Unclear</p>	<p>Blood samples were collected to detect IgG antibodies to SARSCoV-2 in sera and were measured by an enzyme-linked immunosorbent assay (ELISA, five to six months after the second dose) in December 2021 before the onset of the third wave in India.</p> <p>Serology tests: IgG ELISA using the Covid Kawach IgG Microlisa kit</p>	<p>Seroconversion rates: 65/80 (81%)</p> <p>Breakthrough infections:</p> <ul style="list-style-type: none"> • In seropositive group: 11/65 (17%) • In seronegative group: 2/15 (13%) <p>Breakthrough infections requiring hospitalization:</p> <ul style="list-style-type: none"> • In seropositive group: 5/11 (45%) • In seronegative group: 0/2 (0%)

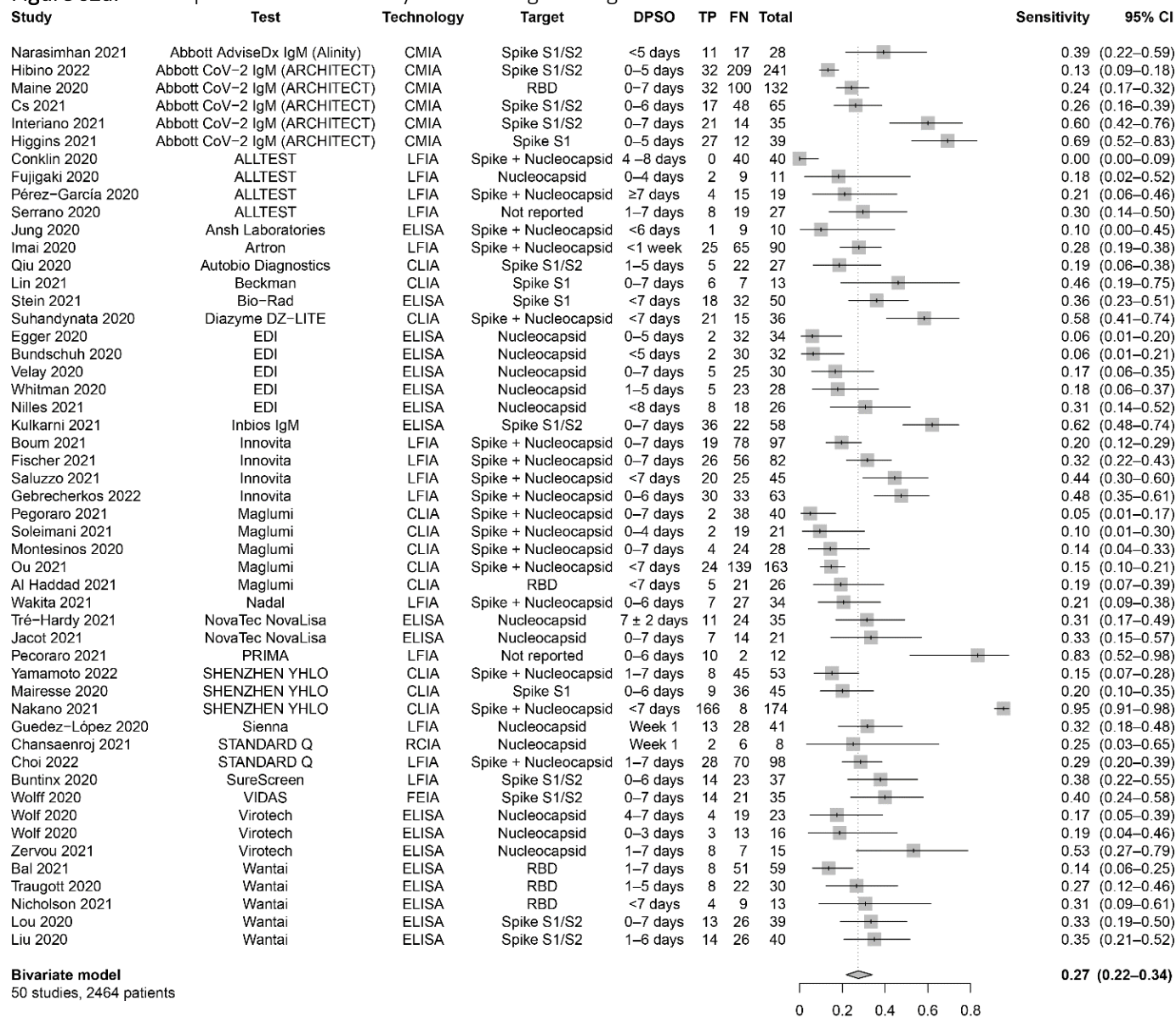
Supplement B

Recommendation: The IDSA panel recommends against using serologic testing to diagnose SARS-CoV-2 infection during the first two weeks following symptom onset (strong recommendation, low certainty of evidence).

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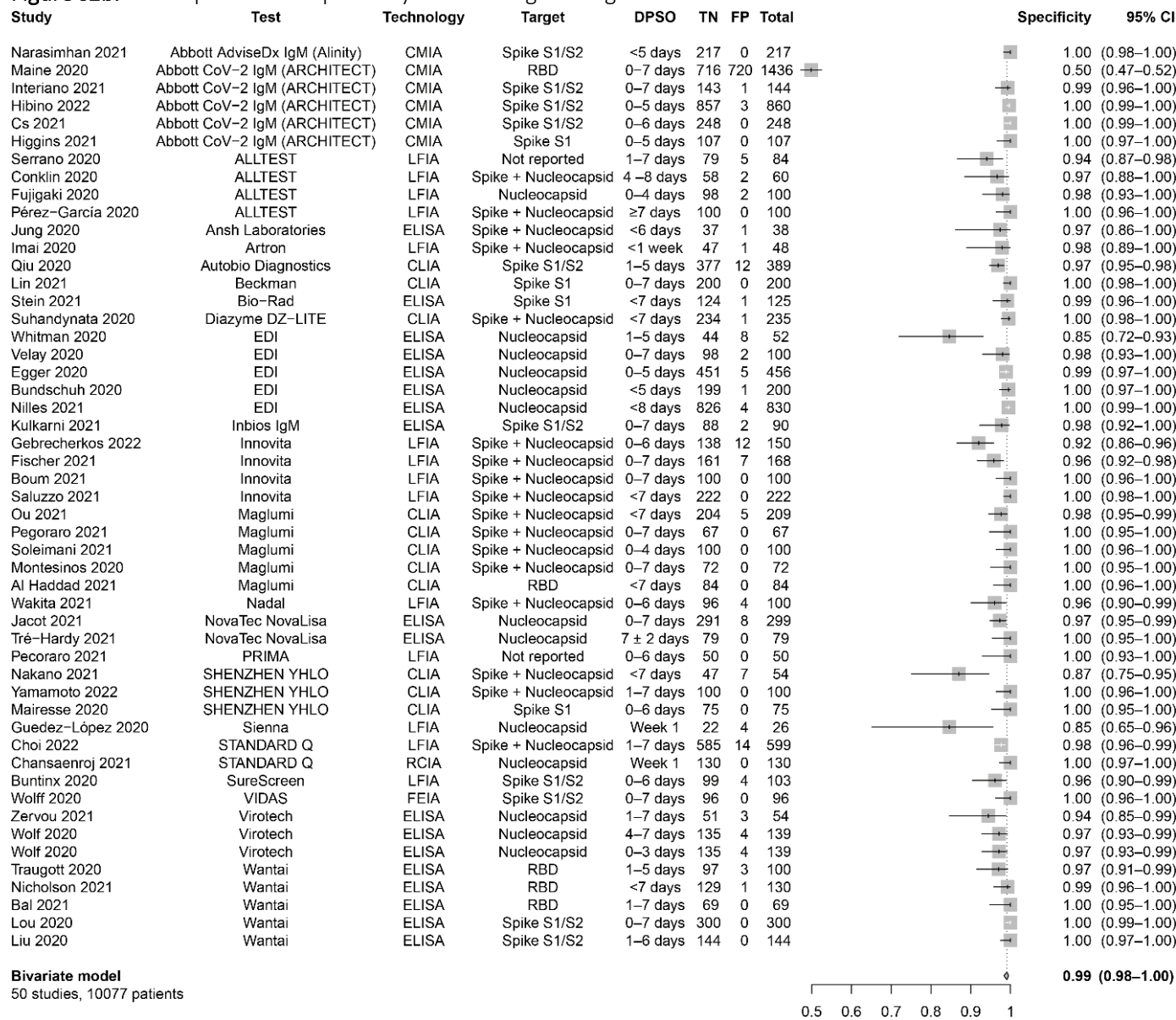
Figure s2a. Forest plot for the sensitivity of week 1 IgM using NAAT as reference standard



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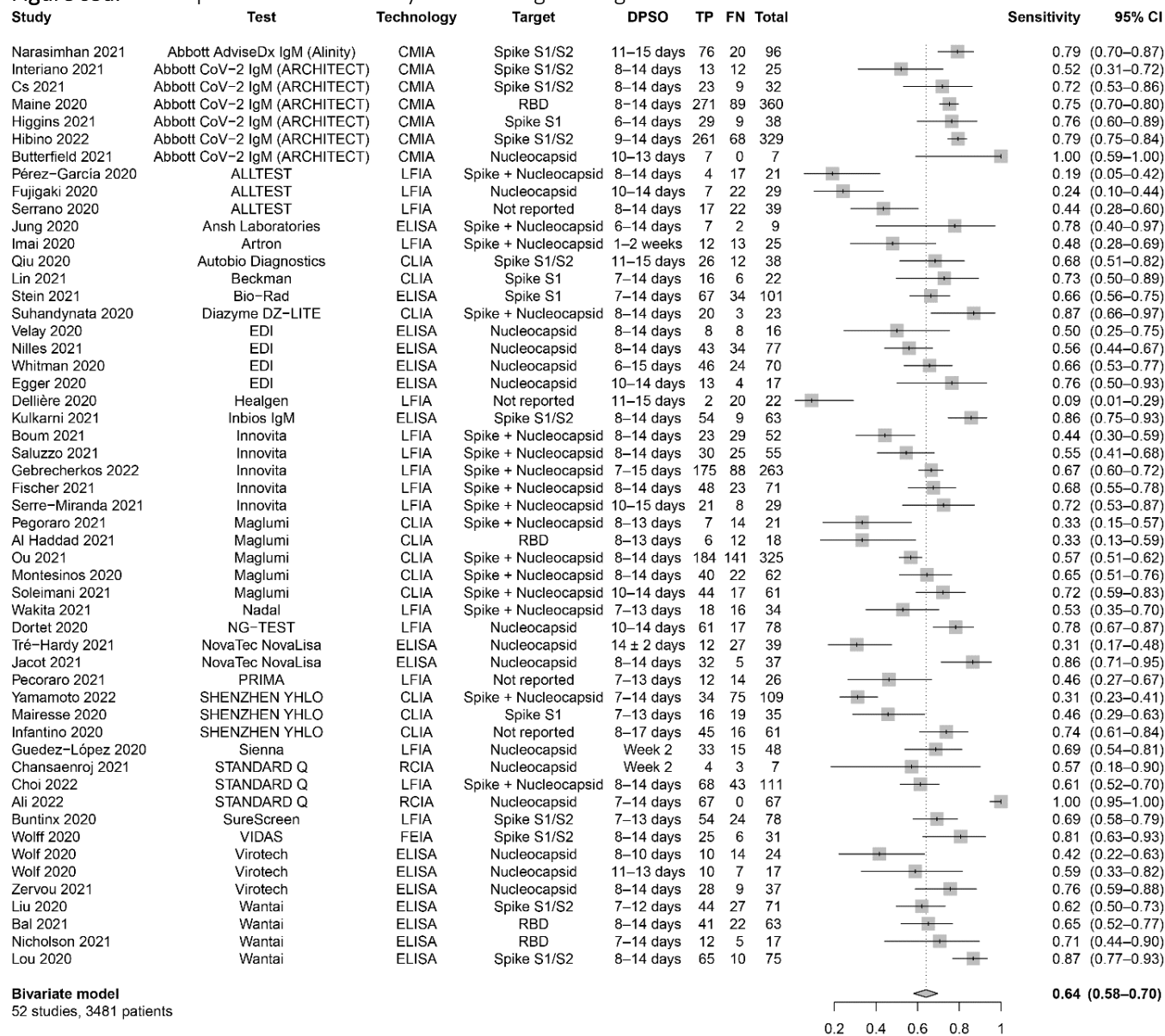
Supplementary Materials

Figure s2b. Forest plot for the specificity of week 1 IgM using NAAT as reference standard



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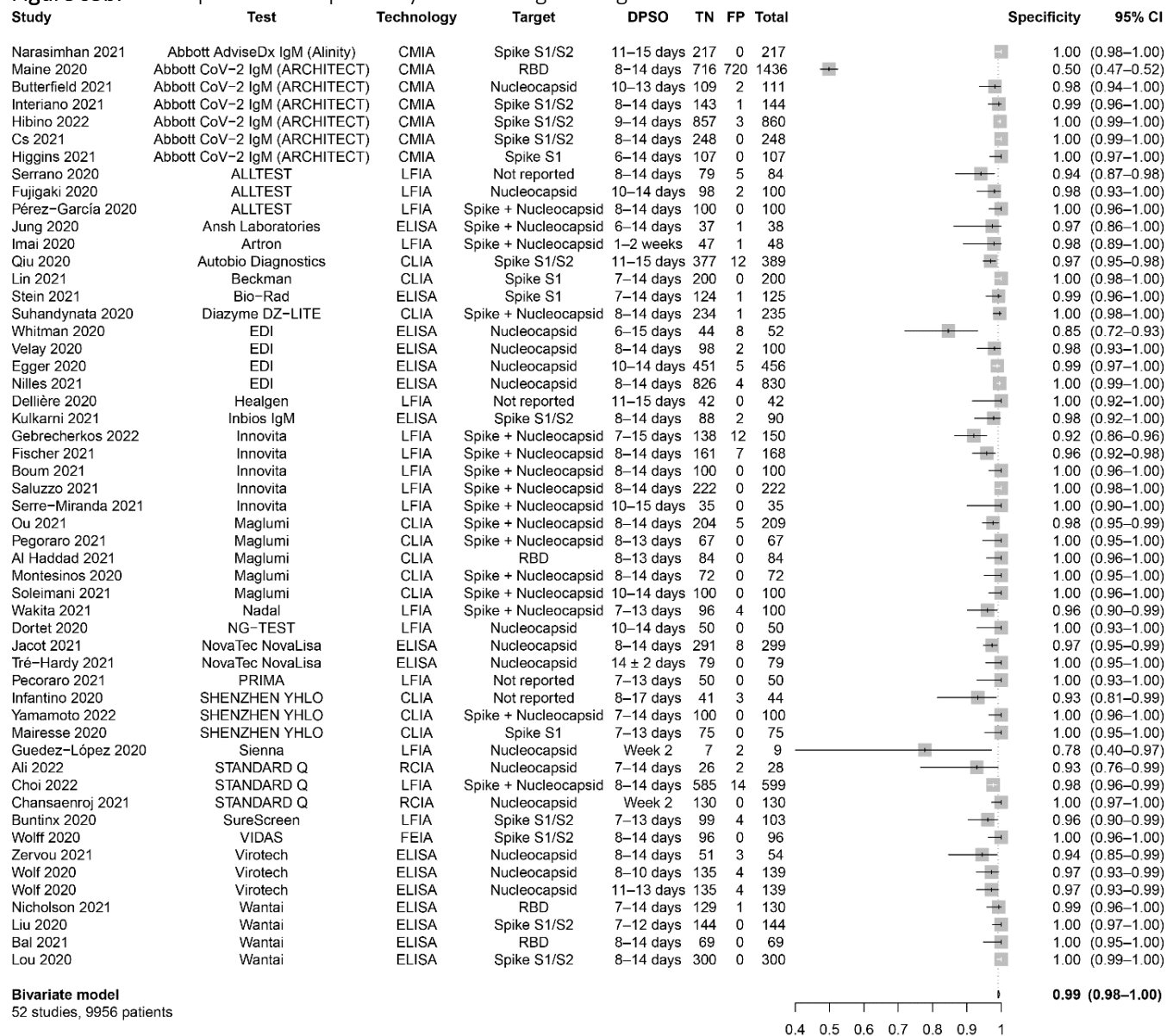
Figure s3a. Forest plot for the sensitivity of week 2 IgM using NAAT as reference standard



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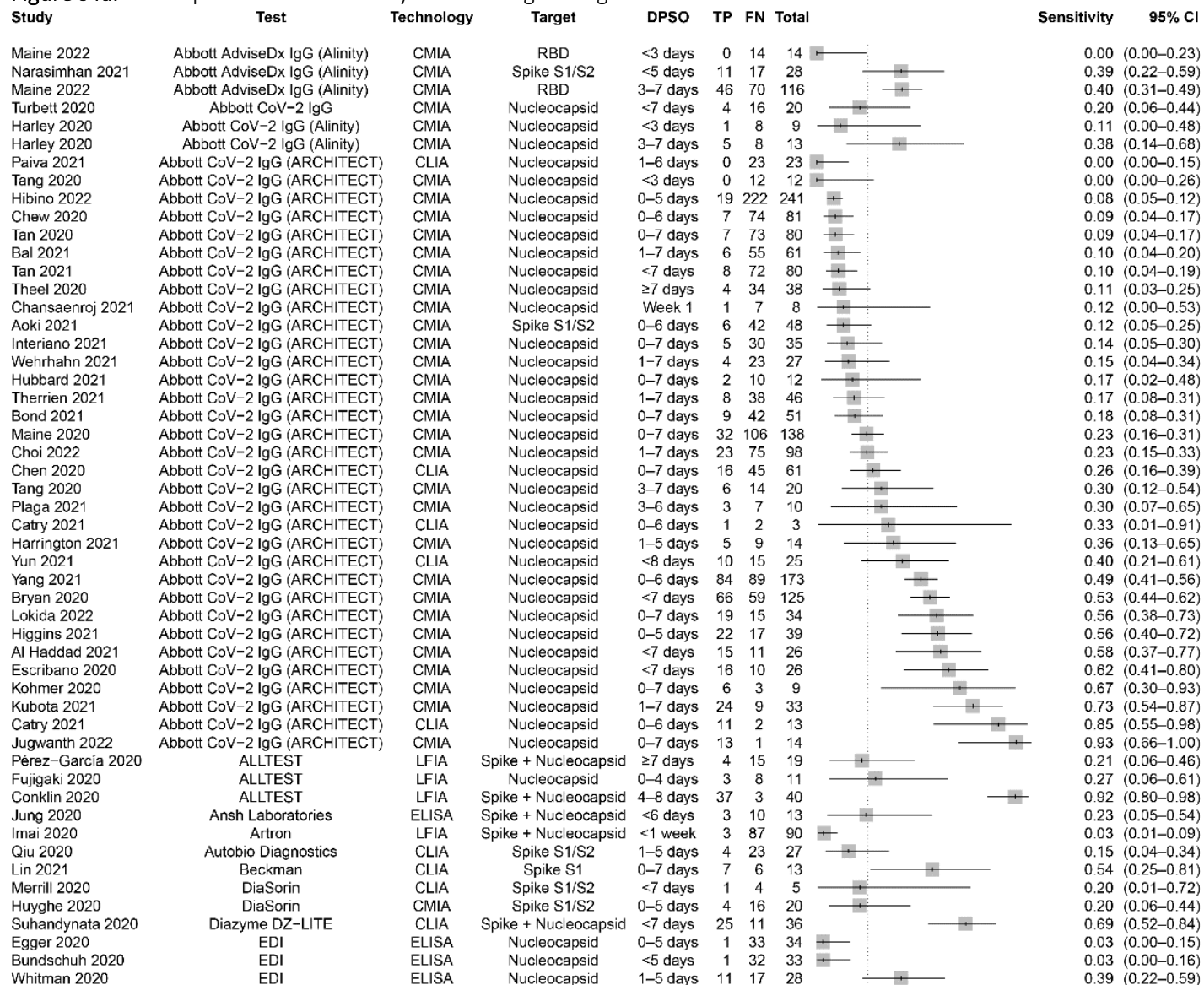
Supplementary Materials

Figure s3b. Forest plot for the specificity of week 2 IgM using NAAT as reference standard



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Figure s4a. Forest plot for the sensitivity of week 1 IgG using NAAT as reference standard

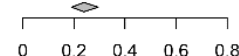


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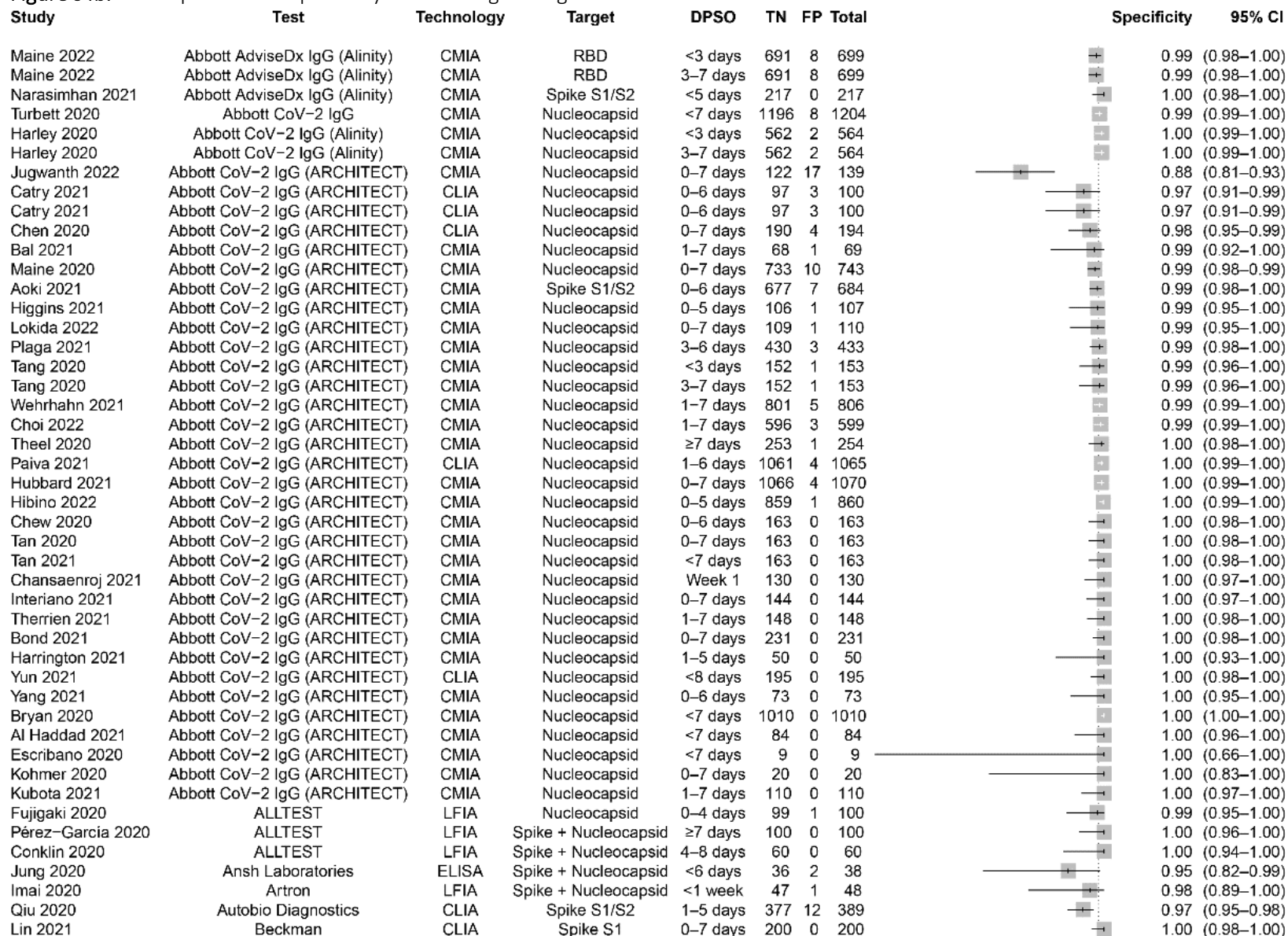
Pegoraro 2021	Euroimmun	ELISA	Spike S1	0–7 days	0	40	40	0.00 (0.00–0.09)
Kittel 2021	Euroimmun	ELISA	Spike S1	1–7 days	0	10	10	0.00 (0.00–0.31)
Nilsson 2021	Euroimmun	ELISA	Spike S1	1–7 days	0	3	3	0.00 (0.00–0.71)
Jacot 2021	Euroimmun	ELISA	Spike S1	0–7 days	0	20	20	0.00 (0.00–0.17)
Caturegli 2020	Euroimmun	ELISA	Spike S1	0–5 days	0	30	30	0.00 (0.00–0.12)
Traugott 2020	Euroimmun	ELISA	Spike S1	1–5 days	1	29	30	0.03 (0.00–0.17)
Cota 2020	Euroimmun	ELISA	Spike S1	<7 days	1	13	14	0.07 (0.00–0.34)
Velay 2020	Euroimmun	ELISA	Spike S1	0–7 days	3	27	30	0.10 (0.02–0.27)
Buchholtz 2021	Euroimmun	ELISA	Spike S1	<5 days	1	9	10	0.10 (0.00–0.45)
Wolf 2020	Euroimmun	ELISA	Spike S1	0–3 days	2	14	16	0.12 (0.02–0.38)
Montesinos 2020	Euroimmun	ELISA	Spike S1	0–7 days	5	24	29	0.17 (0.06–0.36)
Favresse 2021	Euroimmun	ELISA	Nucleocapsid	0–6 days	4	19	23	0.17 (0.05–0.39)
Wolf 2020	Euroimmun	ELISA	Spike S1	4–7 days	4	19	23	0.17 (0.05–0.39)
Nicholson 2021	Euroimmun	ELISA	Nucleocapsid	<7 days	8	32	40	0.20 (0.09–0.36)
Van Elslande 2020	Euroimmun	ELISA	Spike S1	0–6 days	8	29	37	0.22 (0.10–0.38)
Fischer 2021	Euroimmun	ELISA	Spike S1	0–7 days	19	63	82	0.23 (0.15–0.34)
Huber 2021	Euroimmun	ELISA	Spike S1	Week 1	6	16	22	0.27 (0.11–0.50)
Saluzzo 2021	Euroimmun	ELISA	Spike + Nucleocapsid	<7 days	16	29	45	0.36 (0.22–0.51)
Stein 2021	Euroimmun	ELISA	Spike S1	<7 days	29	35	64	0.45 (0.33–0.58)
Kulkarni 2021	Euroimmun	ELISA	Spike S1	0–7 days	38	38	76	0.50 (0.38–0.62)
Serrano 2020	Euroimmun	ELISA	Spike S1	1–7 days	15	13	28	0.54 (0.34–0.72)
Hörber 2020	Euroimmun	ELISA	Spike S1	0–6 days	13	10	23	0.57 (0.34–0.77)
Wolff 2020	Euroimmun	ELISA	Spike S1	0–7 days	21	14	35	0.60 (0.42–0.76)
Boum 2021	Innovita	LFIA	Spike + Nucleocapsid	0–7 days	14	83	97	0.14 (0.08–0.23)
Gebrecherkos 2022	Innovita	LFIA	Spike + Nucleocapsid	0–6 days	17	46	63	0.27 (0.17–0.40)
Gebrecherkos 2022	Innovita	LFIA	Spike + Nucleocapsid	7–15 days	129	134	263	0.49 (0.43–0.55)
Yang 2020	Luminex xMAP	FIA	Spike + Nucleocapsid	0–7 days	9	30	39	0.23 (0.11–0.39)
Soleimani 2021	Maglumi	CLIA	Spike + Nucleocapsid	0–4 days	5	16	21	0.24 (0.08–0.47)
Ou 2021	Maglumi	CLIA	Spike + Nucleocapsid	<7 days	43	120	163	0.26 (0.20–0.34)
Wakita 2021	Nadal	LFIA	Spike + Nucleocapsid	0–6 days	7	27	34	0.21 (0.09–0.38)
Yassine 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	≥7 days	18	10	28	0.64 (0.44–0.81)
Tré-Hardy 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	7 ± 2 days	25	10	35	0.71 (0.54–0.85)
Pecoraro 2021	PRIMA	LFIA	Not reported	0–6 days	4	8	12	0.33 (0.10–0.65)
Mairesse 2020	SHENZHEN YHLO	CLIA	Spike S1	0–6 days	11	34	45	0.24 (0.13–0.40)
Nakano 2021	SHENZHEN YHLO	CLIA	Spike + Nucleocapsid	<7 days	162	12	174	0.93 (0.88–0.96)
Florin 2021	Siemens CV2G	CLIA	Spike S1	<4 days	1	16	17	0.06 (0.00–0.29)
Florin 2021	Siemens CV2G	CLIA	Spike S1	4–7 days	4	27	31	0.13 (0.04–0.30)
Igawa 2021	Siemens CV2G	CLIA	Spike S1	0–6 days	7	33	40	0.17 (0.07–0.33)
Guedez-López 2020	Sienna	LFIA	Nucleocapsid	Week 1	11	30	41	0.27 (0.14–0.43)
Yamamoto 2022	SuperFlex PerkinElmer	CLIA	Spike S1/S2	1–7 days	11	42	53	0.21 (0.11–0.34)
Buntinx 2020	SureScreen	LFIA	Spike S1/S2	0–6 days	3	34	37	0.08 (0.02–0.22)
Zervou 2021	Virotech	ELISA	Nucleocapsid	1–7 days	7	8	15	0.47 (0.21–0.73)
Lou 2020	Wantai	ELISA	Spike S1/S2	0–7 days	13	26	39	0.33 (0.19–0.50)

Bivariate model
88 studies, 4250 patients



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Figure s4b. Forest plot for the specificity of week 1 IgG using NAAT as reference standard



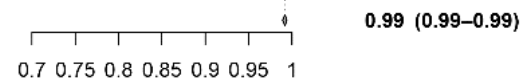
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Huyghe 2020	DiaSorin	CMIA	Spike S1/S2	0–5 days	114	6	120	0.95 (0.89–0.98)
Merrill 2020	DiaSorin	CLIA	Spike S1/S2	<7 days	172	2	174	0.99 (0.96–1.00)
Suhandynata 2020	Diazyme DZ-LITE	CLIA	Spike + Nucleocapsid	<7 days	233	2	235	0.99 (0.97–1.00)
Whitman 2020	EDI	ELISA	Nucleocapsid	1–5 days	50	2	52	0.96 (0.87–1.00)
Egger 2020	EDI	ELISA	Nucleocapsid	0–5 days	451	5	456	0.99 (0.97–1.00)
Bundschuh 2020	EDI	ELISA	Nucleocapsid	<5 days	198	2	200	0.99 (0.96–1.00)
Kittel 2021	Euroimmun	ELISA	Spike S1	1–7 days	234	15	249	0.94 (0.90–0.97)
Cota 2020	Euroimmun	ELISA	Spike S1	<7 days	111	5	116	0.96 (0.90–0.99)
Wolff 2020	Euroimmun	ELISA	Spike S1	0–7 days	92	4	96	0.96 (0.90–0.99)
Saluzzo 2021	Euroimmun	ELISA	Spike + Nucleocapsid	<7 days	213	9	222	0.96 (0.92–0.98)
Van Elslande 2020	Euroimmun	ELISA	Spike S1	0–6 days	99	4	103	0.96 (0.90–0.99)
Favresse 2021	Euroimmun	ELISA	Nucleocapsid	0–6 days	136	5	141	0.96 (0.92–0.99)
Fischer 2021	Euroimmun	ELISA	Spike S1	0–7 days	163	5	168	0.97 (0.93–0.99)
Traugott 2020	Euroimmun	ELISA	Spike S1	1–5 days	98	2	100	0.98 (0.93–1.00)
Nilsson 2021	Euroimmun	ELISA	Spike S1	1–7 days	197	3	200	0.98 (0.96–1.00)
Pegoraro 2021	Euroimmun	ELISA	Spike S1	0–7 days	66	1	67	0.99 (0.92–1.00)
Montesinos 2020	Euroimmun	ELISA	Spike S1	0–7 days	71	1	72	0.99 (0.93–1.00)
Caturegli 2020	Euroimmun	ELISA	Spike S1	0–5 days	561	7	568	0.99 (0.97–1.00)
Stein 2021	Euroimmun	ELISA	Spike S1	<7 days	173	2	175	0.99 (0.96–1.00)
Velay 2020	Euroimmun	ELISA	Spike S1	0–7 days	99	1	100	0.99 (0.95–1.00)
Huber 2021	Euroimmun	ELISA	Spike S1	Week 1	105	1	106	0.99 (0.95–1.00)
Nicholson 2021	Euroimmun	ELISA	Nucleocapsid	<7 days	219	2	221	0.99 (0.97–1.00)
Buchholtz 2021	Euroimmun	ELISA	Spike S1	<5 days	236	2	238	0.99 (0.97–1.00)
Wolf 2020	Euroimmun	ELISA	Spike S1	0–3 days	138	1	139	0.99 (0.96–1.00)
Wolf 2020	Euroimmun	ELISA	Spike S1	4–7 days	138	1	139	0.99 (0.96–1.00)
Jacot 2021	Euroimmun	ELISA	Spike S1	0–7 days	294	2	296	0.99 (0.98–1.00)
Kulkarni 2021	Euroimmun	ELISA	Spike S1	0–7 days	90	0	90	1.00 (0.96–1.00)
Serrano 2020	Euroimmun	ELISA	Spike S1	1–7 days	84	0	84	1.00 (0.96–1.00)
Hörber 2020	Euroimmun	ELISA	Spike S1	0–6 days	123	0	123	1.00 (0.97–1.00)
Gebrecherkos 2022	Innovita	LFIA	Spike + Nucleocapsid	0–6 days	146	4	150	0.97 (0.93–0.99)
Gebrecherkos 2022	Innovita	LFIA	Spike + Nucleocapsid	7–15 days	146	4	150	0.97 (0.93–0.99)
Boum 2021	Innovita	LFIA	Spike + Nucleocapsid	0–7 days	100	0	100	1.00 (0.96–1.00)
Yang 2020	Luminex xMAP	FIA	Spike + Nucleocapsid	0–7 days	254	2	256	0.99 (0.97–1.00)
Ou 2021	Maglumi	CLIA	Spike + Nucleocapsid	<7 days	205	4	209	0.98 (0.95–0.99)
Soleimani 2021	Maglumi	CLIA	Spike + Nucleocapsid	0–4 days	100	0	100	1.00 (0.96–1.00)
Wakita 2021	Nadal	LFIA	Spike + Nucleocapsid	0–6 days	99	1	100	0.99 (0.95–1.00)
Yassine 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	≥7 days	60	10	70	0.86 (0.75–0.93)
Tré-Hardy 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	7 ± 2 days	78	1	79	0.99 (0.93–1.00)
Pecoraro 2021	PRIMA	LFIA	Not reported	0–6 days	50	0	50	1.00 (0.93–1.00)
Mairesse 2020	SHENZHEN YHLO	CLIA	Spike S1	0–6 days	74	1	75	0.99 (0.93–1.00)
Nakano 2021	SHENZHEN YHLO	CLIA	Spike + Nucleocapsid	<7 days	54	0	54	1.00 (0.93–1.00)
Igawa 2021	Siemens CV2G	CLIA	Spike S1	0–6 days	99	1	100	0.99 (0.95–1.00)
Florin 2021	Siemens CV2G	CLIA	Spike S1	<4 days	90	0	90	1.00 (0.96–1.00)
Florin 2021	Siemens CV2G	CLIA	Spike S1	4–7 days	90	0	90	1.00 (0.96–1.00)
Guedez-López 2020	Sienna	LFIA	Nucleocapsid	Week 1	25	1	26	0.96 (0.80–1.00)
Yamamoto 2022	SuperFlex PerkinElmer	CLIA	Spike S1/S2	1–7 days	100	0	100	1.00 (0.96–1.00)
Buntinx 2020	SureScreen	LFIA	Spike S1/S2	0–6 days	103	1	104	0.99 (0.95–1.00)
Zervou 2021	Virotech	ELISA	Nucleocapsid	1–7 days	54	0	54	1.00 (0.93–1.00)
Lou 2020	Wantai	ELISA	Spike S1/S2	0–7 days	100	0	100	1.00 (0.96–1.00)

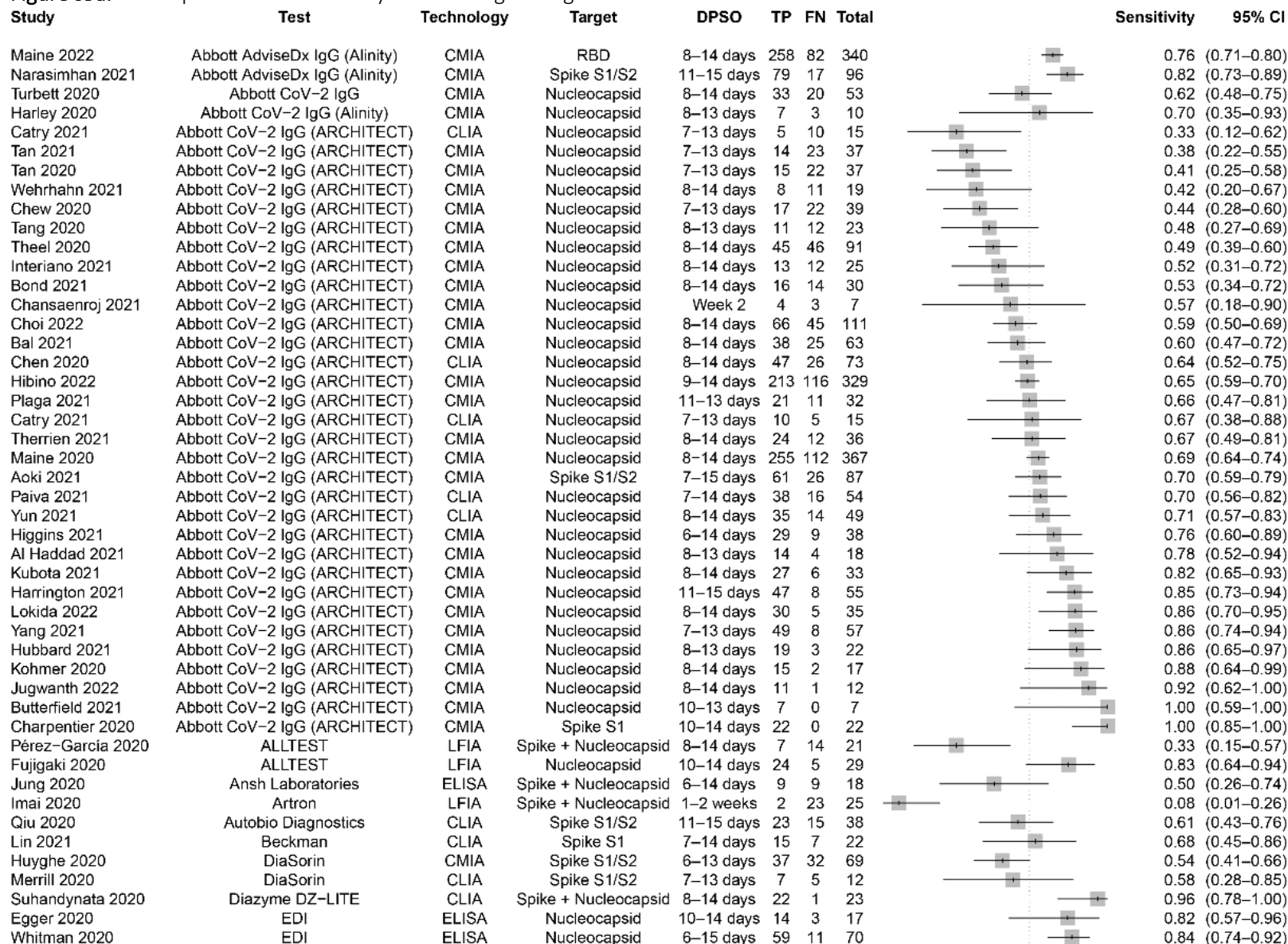
Bivariate model

88 studies, 22321 patients






























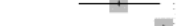










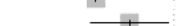







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Figure s5a. Forest plot for the sensitivity of week 2 IgG using NAAT as reference standard



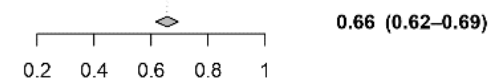
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Kittel 2021	Euroimmun	ELISA	Spike S1	8–14 days	3	7	10		0.30 (0.07–0.65)
Marlet 2020	Euroimmun	ELISA	Spike S1	7–13 days	4	9	13		0.31 (0.09–0.61)
Pegoraro 2021	Euroimmun	ELISA	Spike S1	8–13 days	8	13	21		0.38 (0.18–0.62)
Nicholson 2021	Euroimmun	ELISA	Nucleocapsid	7–14 days	14	20	34		0.41 (0.25–0.59)
Saluzzo 2021	Euroimmun	ELISA	Spike + Nucleocapsid	8–14 days	23	32	55		0.42 (0.29–0.56)
Wolf 2020	Euroimmun	ELISA	Spike S1	8–10 days	11	13	24		0.46 (0.26–0.67)
Cota 2020	Euroimmun	ELISA	Spike S1	7–14 days	22	25	47		0.47 (0.32–0.62)
Velay 2020	Euroimmun	ELISA	Spike S1	8–14 days	8	8	16		0.50 (0.25–0.75)
Caturegli 2020	Euroimmun	ELISA	Spike S1	10–13 days	38	36	74		0.51 (0.39–0.63)
Van Elslande 2020	Euroimmun	ELISA	Spike S1	7–13 days	43	35	78		0.55 (0.43–0.66)
Jacot 2021	Euroimmun	ELISA	Spike S1	8–14 days	18	14	32		0.56 (0.38–0.74)
Nilsson 2021	Euroimmun	ELISA	Spike S1	8–14 days	13	10	23		0.57 (0.34–0.77)
Fischer 2021	Euroimmun	ELISA	Spike S1	8–14 days	44	27	71		0.62 (0.50–0.73)
Stein 2021	Euroimmun	ELISA	Spike S1	7–14 days	73	43	116		0.63 (0.53–0.72)
Buchholtz 2021	Euroimmun	ELISA	Spike S1	10–14 days	18	10	28		0.64 (0.44–0.81)
Tanis 2021	Euroimmun	ELISA	Spike S1	10–15 days	85	46	131		0.65 (0.56–0.73)
Montesinos 2020	Euroimmun	ELISA	Spike S1	8–14 days	41	21	62		0.66 (0.53–0.78)
Huber 2021	Euroimmun	ELISA	Spike S1	Week 2	19	9	28		0.68 (0.48–0.84)
Favresse 2021	Euroimmun	ELISA	Nucleocapsid	7–13 days	19	8	27		0.70 (0.50–0.86)
Wolff 2020	Euroimmun	ELISA	Spike S1	8–14 days	22	9	31		0.71 (0.52–0.86)
Wolf 2020	Euroimmun	ELISA	Spike S1	11–13 days	13	4	17		0.76 (0.50–0.93)
Serre–Miranda 2021	Euroimmun	ELISA	Spike S1	10–15 days	26	7	33		0.79 (0.61–0.91)
Vauloup–Fellous 2021	Euroimmun	ELISA	Spike S1	10–14 days	71	17	88		0.81 (0.71–0.88)
Serrano 2020	Euroimmun	ELISA	Spike S1	8–14 days	32	7	39		0.82 (0.66–0.92)
Hörber 2020	Euroimmun	ELISA	Spike S1	7–13 days	26	5	31		0.84 (0.66–0.95)
Kulkarni 2021	Euroimmun	ELISA	Spike S1	8–14 days	54	9	63		0.86 (0.75–0.93)
Dellièvre 2020	Healgen	LFIA	Not reported	11–15 days	1	21	22		0.05 (0.00–0.23)
Boum 2021	Innovita	LFIA	Spike + Nucleocapsid	8–14 days	24	28	52		0.46 (0.32–0.61)
Yang 2020	Luminex xMAP	FIA	Spike + Nucleocapsid	8–14 days	26	16	42		0.62 (0.46–0.76)
Ou 2021	Maglumi	CLIA	Spike + Nucleocapsid	8–14 days	216	109	325		0.66 (0.61–0.72)
Soleimani 2021	Maglumi	CLIA	Spike + Nucleocapsid	10–14 days	46	15	61		0.75 (0.63–0.86)
Wakita 2021	Nadal	LFIA	Spike + Nucleocapsid	7–13 days	19	15	34		0.56 (0.38–0.73)
Dortet 2020	NG-TEST	LFIA	Nucleocapsid	10–14 days	58	20	78		0.74 (0.63–0.84)
Yassine 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	8–14 days	35	5	40		0.88 (0.73–0.96)
Tré–Hardy 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	14 ± 2 days	35	4	39		0.90 (0.76–0.97)
Pecoraro 2021	PRIMA	LFIA	Not reported	7–13 days	20	6	26		0.77 (0.56–0.91)
Mairesse 2020	SHENZHEN YHLO	CLIA	Spike S1	7–13 days	24	11	35		0.69 (0.51–0.83)
Infantino 2020	SHENZHEN YHLO	CLIA	Not reported	8–17 days	47	14	61		0.77 (0.65–0.87)
Florin 2021	Siemens CV2G	CLIA	Spike S1	8–10 days	8	13	21		0.38 (0.18–0.62)
Igawa 2021	Siemens CV2G	CLIA	Spike S1	7–13 days	28	28	56		0.50 (0.36–0.64)
Florin 2021	Siemens CV2G	CLIA	Spike S1	11–14 days	18	14	32		0.56 (0.38–0.74)
Guedez–López 2020	Sienna	LFIA	Nucleocapsid	Week 2	33	15	48		0.69 (0.54–0.81)
Yamamoto 2022	SuperFlex PerkinElmer	CLIA	Spike S1/S2	7–14 days	61	48	109		0.56 (0.46–0.65)
Buntinx 2020	SureScreen	LFIA	Spike S1/S2	7–13 days	40	38	78		0.51 (0.40–0.63)
Zervou 2021	Virotech	ELISA	Nucleocapsid	8–14 days	33	4	37		0.89 (0.75–0.97)
Lou 2020	Wantai	ELISA	Spike S1/S2	8–14 days	57	18	75		0.76 (0.65–0.85)

Bivariate model

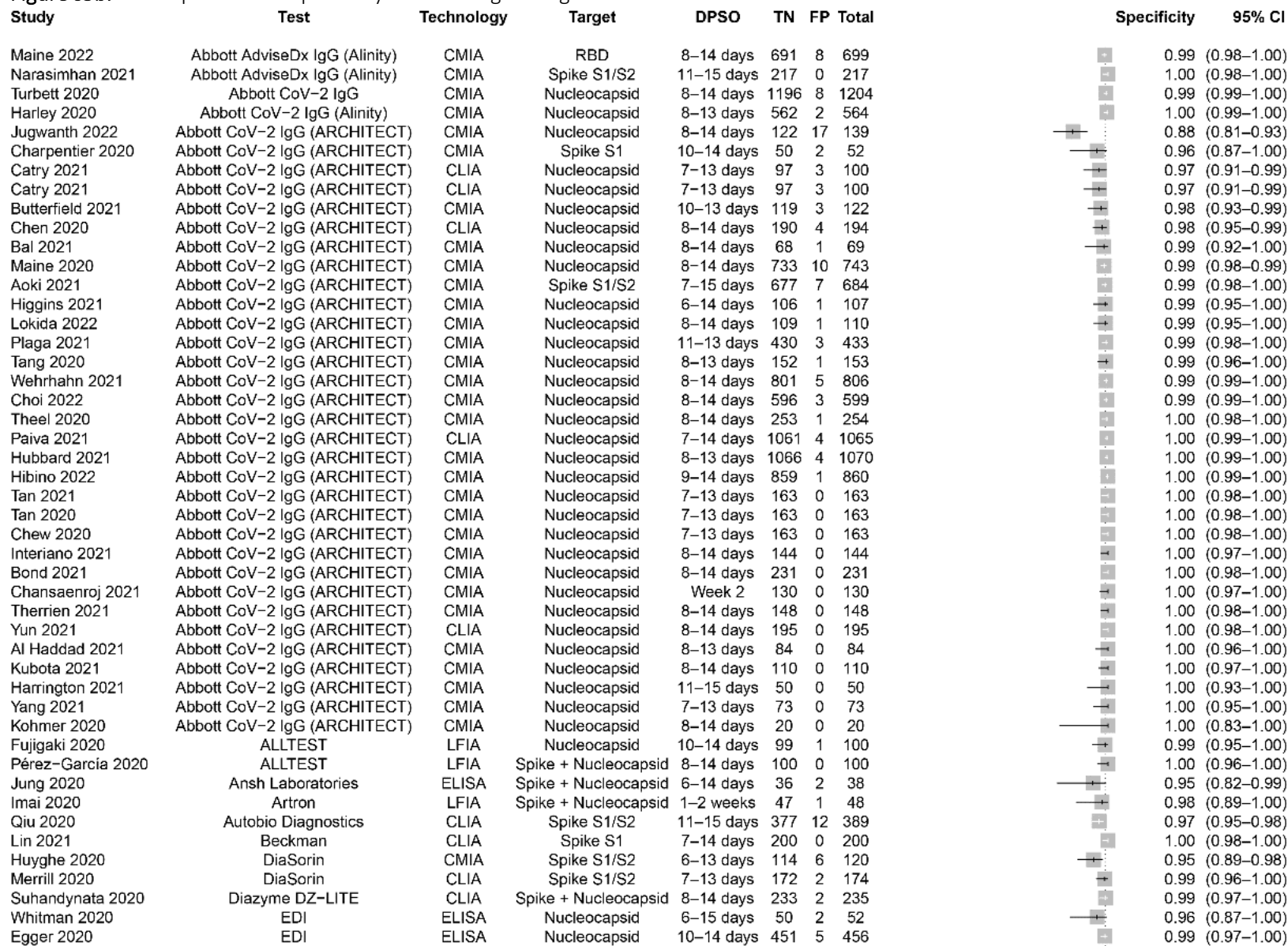
90 studies, 5161 patients



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Figure s5b. Forest plot for the specificity of week 2 IgG using NAAT as reference standard



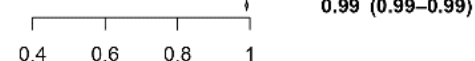
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Tanis 2021	Euroimmun	ELISA	Spike S1	10–15 days	33	3	36	0.92 (0.78–0.98)
Marlet 2020	Euroimmun	ELISA	Spike S1	7–13 days	82	7	89	0.92 (0.84–0.97)
Kittel 2021	Euroimmun	ELISA	Spike S1	8–14 days	234	15	249	0.94 (0.90–0.97)
Vauloup-Fellous 2021	Euroimmun	ELISA	Spike S1	10–14 days	333	21	354	0.94 (0.91–0.96)
Cota 2020	Euroimmun	ELISA	Spike S1	7–14 days	111	5	116	0.96 (0.90–0.99)
Wolff 2020	Euroimmun	ELISA	Spike S1	8–14 days	92	4	96	0.96 (0.90–0.99)
Saluzzo 2021	Euroimmun	ELISA	Spike + Nucleocapsid	8–14 days	213	9	222	0.96 (0.92–0.98)
Van Elslande 2020	Euroimmun	ELISA	Spike S1	7–13 days	99	4	103	0.96 (0.90–0.99)
Favresse 2021	Euroimmun	ELISA	Nucleocapsid	7–13 days	136	5	141	0.96 (0.92–0.99)
Fischer 2021	Euroimmun	ELISA	Spike S1	8–14 days	163	5	168	0.97 (0.93–0.99)
Nilsson 2021	Euroimmun	ELISA	Spike S1	8–14 days	197	3	200	0.98 (0.96–1.00)
Pegoraro 2021	Euroimmun	ELISA	Spike S1	8–13 days	66	1	67	0.99 (0.92–1.00)
Caturegli 2020	Euroimmun	ELISA	Spike S1	10–13 days	561	7	568	0.99 (0.97–1.00)
Stein 2021	Euroimmun	ELISA	Spike S1	7–14 days	173	2	175	0.99 (0.96–1.00)
Velay 2020	Euroimmun	ELISA	Spike S1	8–14 days	99	1	100	0.99 (0.95–1.00)
Huber 2021	Euroimmun	ELISA	Spike S1	Week 2	105	1	106	0.99 (0.95–1.00)
Nicholson 2021	Euroimmun	ELISA	Nucleocapsid	7–14 days	219	2	221	0.99 (0.97–1.00)
Buchholtz 2021	Euroimmun	ELISA	Spike S1	10–14 days	236	2	238	0.99 (0.97–1.00)
Wolf 2020	Euroimmun	ELISA	Spike S1	8–10 days	138	1	139	0.99 (0.96–1.00)
Wolf 2020	Euroimmun	ELISA	Spike S1	11–13 days	138	1	139	0.99 (0.96–1.00)
Jacot 2021	Euroimmun	ELISA	Spike S1	8–14 days	294	2	296	0.99 (0.98–1.00)
Montesinos 2020	Euroimmun	ELISA	Spike S1	8–14 days	72	0	72	1.00 (0.95–1.00)
Serre-Miranda 2021	Euroimmun	ELISA	Spike S1	10–15 days	38	0	38	1.00 (0.91–1.00)
Serrano 2020	Euroimmun	ELISA	Spike S1	8–14 days	84	0	84	1.00 (0.96–1.00)
Hörber 2020	Euroimmun	ELISA	Spike S1	7–13 days	123	0	123	1.00 (0.97–1.00)
Kulkarni 2021	Euroimmun	ELISA	Spike S1	8–14 days	90	0	90	1.00 (0.96–1.00)
Dellièrre 2020	Healgen	LFIA	Not reported	11–15 days	42	0	42	1.00 (0.92–1.00)
Boum 2021	Innovita	LFIA	Spike + Nucleocapsid	8–14 days	100	0	100	1.00 (0.96–1.00)
Yang 2020	Luminex xMAP	FIA	Spike + Nucleocapsid	8–14 days	254	2	256	0.99 (0.97–1.00)
Ou 2021	Maglumi	CLIA	Spike + Nucleocapsid	8–14 days	205	4	209	0.98 (0.95–0.99)
Soleimani 2021	Maglumi	CLIA	Spike + Nucleocapsid	10–14 days	100	0	100	1.00 (0.96–1.00)
Wakita 2021	Nadal	LFIA	Spike + Nucleocapsid	7–13 days	99	1	100	0.99 (0.95–1.00)
Dortet 2020	NG-TEST	LFIA	Nucleocapsid	10–14 days	50	0	50	1.00 (0.93–1.00)
Yassine 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	8–14 days	60	10	70	0.86 (0.75–0.93)
Tré-Hardy 2021	NovaTec NovaLisa	ELISA	Nucleocapsid	14 ± 2 days	78	1	79	0.99 (0.93–1.00)
Pecoraro 2021	PRIMA	LFIA	Not reported	7–13 days	50	0	50	1.00 (0.93–1.00)
Mairesse 2020	SHENZHEN YHLO	CLIA	Spike S1	7–13 days	74	1	75	0.99 (0.93–1.00)
Infantino 2020	SHENZHEN YHLO	CLIA	Not reported	8–17 days	44	0	44	1.00 (0.92–1.00)
Igawa 2021	Siemens CV2G	CLIA	Spike S1	7–13 days	99	1	100	0.99 (0.95–1.00)
Florin 2021	Siemens CV2G	CLIA	Spike S1	8–10 days	90	0	90	1.00 (0.96–1.00)
Florin 2021	Siemens CV2G	CLIA	Spike S1	11–14 days	90	0	90	1.00 (0.96–1.00)
Guedez-López 2020	Sienna	LFIA	Nucleocapsid	Week 2	5	4	9	0.56 (0.21–0.86)
Yamamoto 2022	SuperFlex PerkinElmer	CLIA	Spike S1/S2	7–14 days	100	0	100	1.00 (0.96–1.00)
Buntinx 2020	SureScreen	LFIA	Spike S1/S2	7–13 days	103	1	104	0.99 (0.95–1.00)
Zervou 2021	Virotech	ELISA	Nucleocapsid	8–14 days	54	0	54	1.00 (0.93–1.00)
Lou 2020	Wantai	ELISA	Spike S1/S2	8–14 days	100	0	100	1.00 (0.96–1.00)

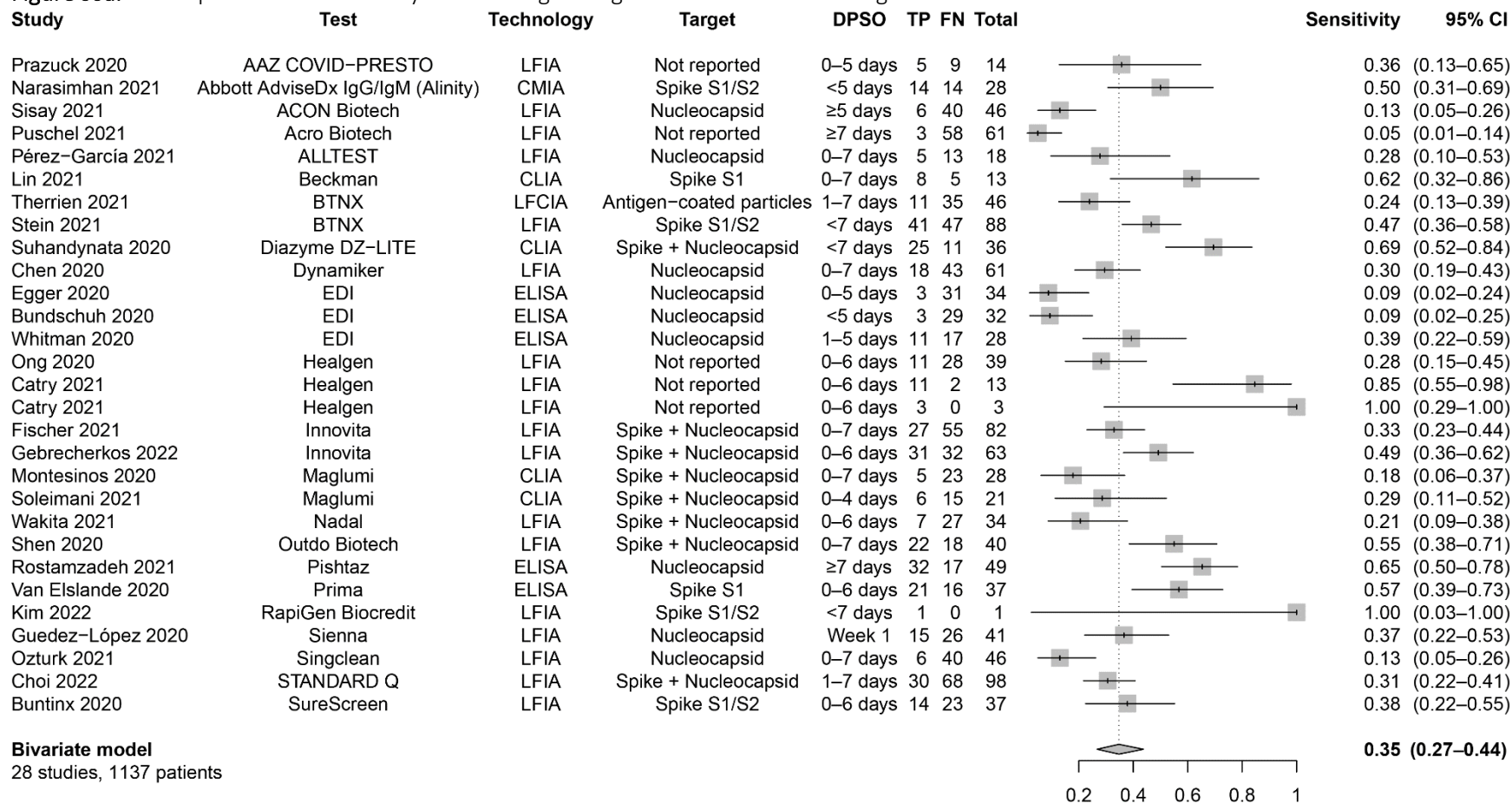
Bivariate model

90 studies, 19982 patients



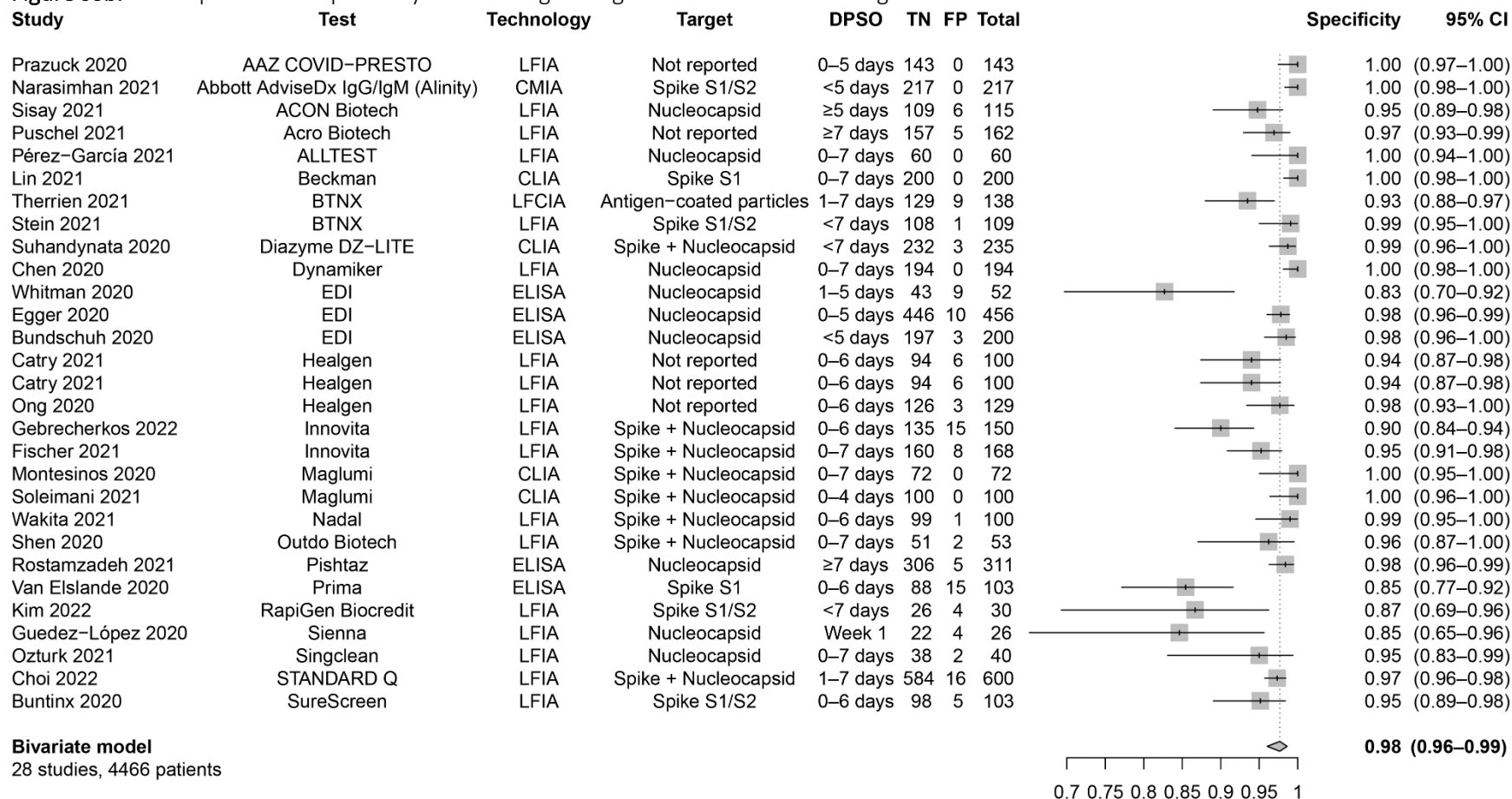
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Figure s6a. Forest plot for the sensitivity of week 1 IgM or IgG combination tests using NAAT as reference standard



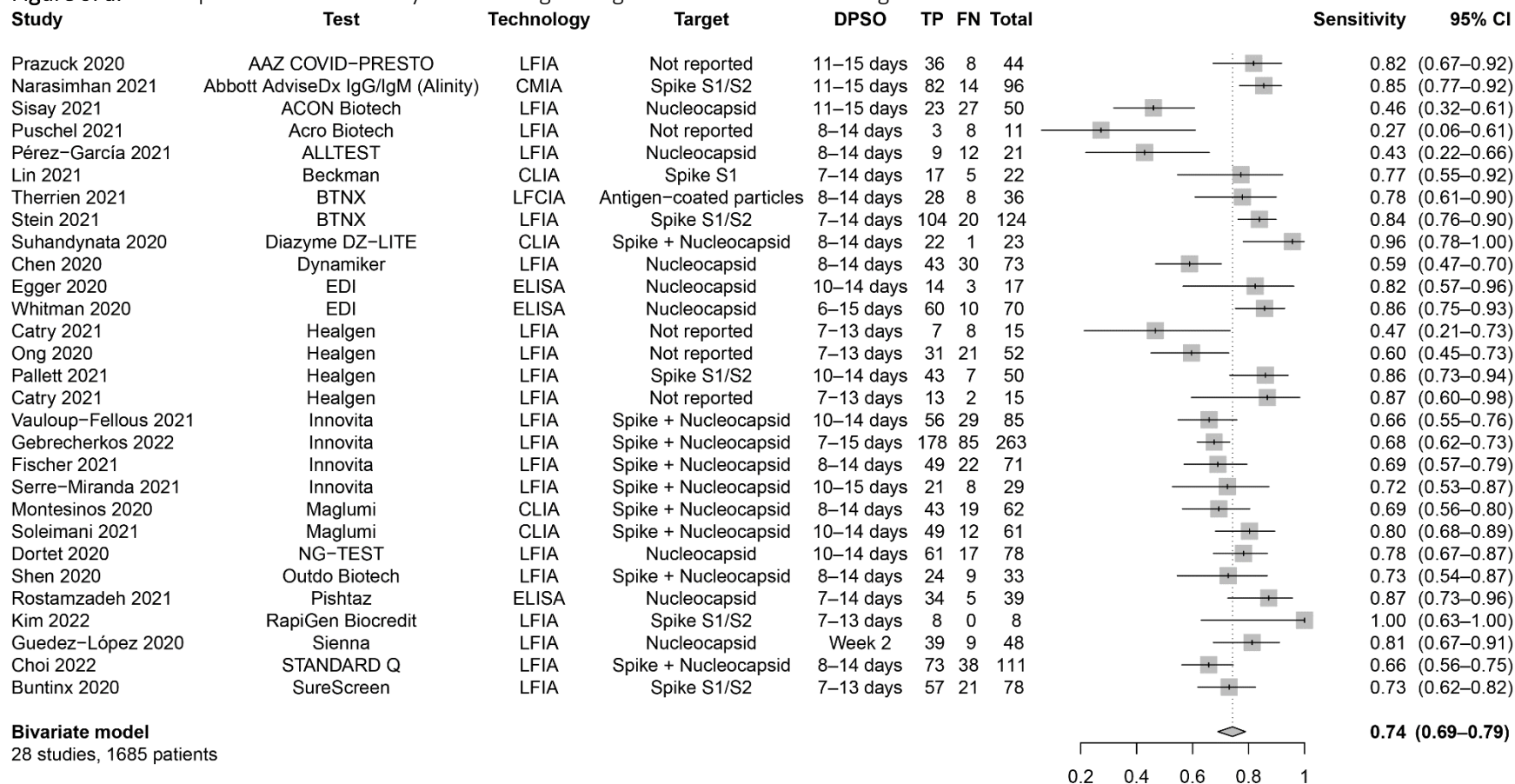
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Figure s6b. Forest plot for the specificity of week 1 IgM or IgG combination tests using NAAT as reference standard



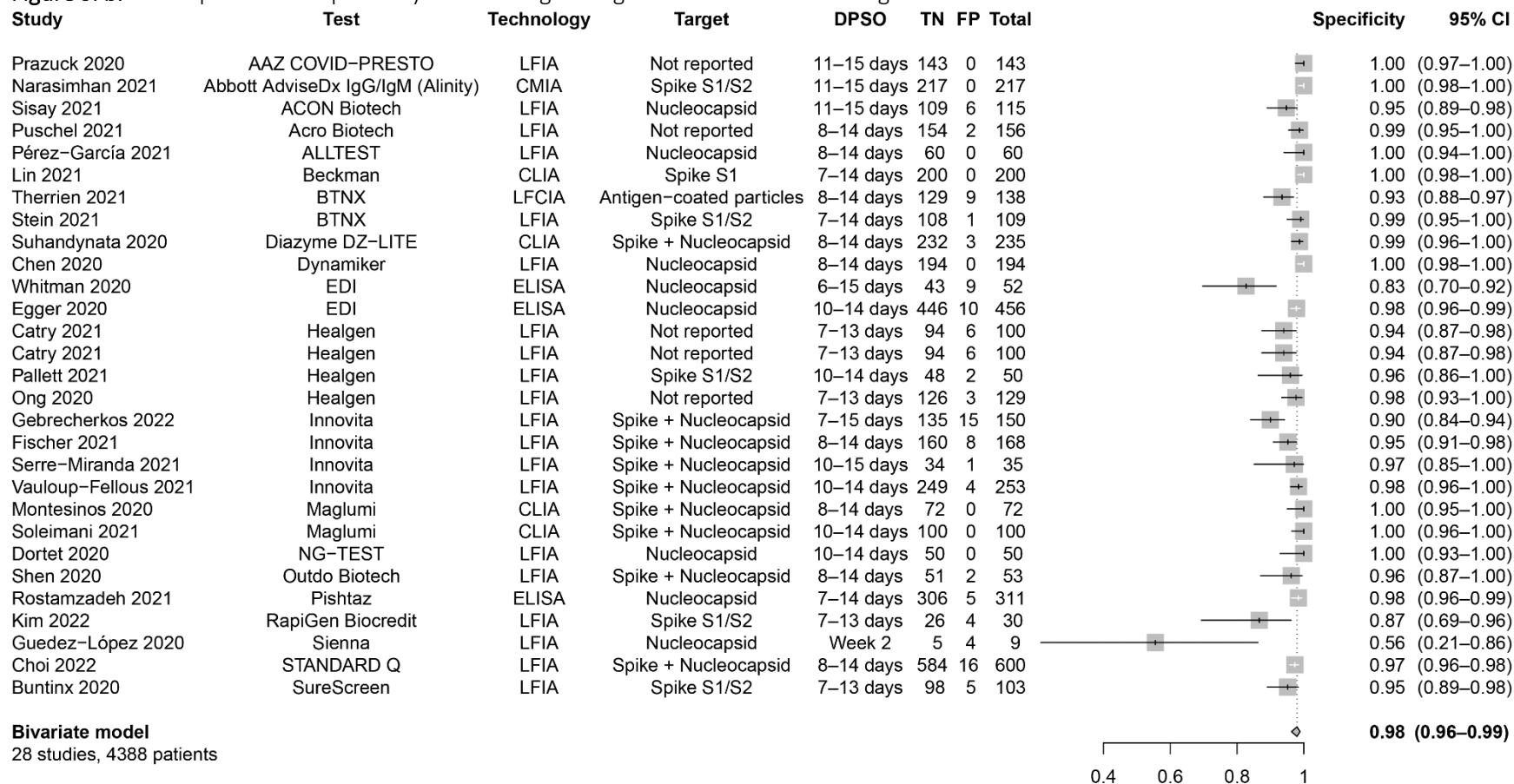
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Figure s7a. Forest plot for the sensitivity of week 2 IgM or IgG combination tests using NAAT as reference standard



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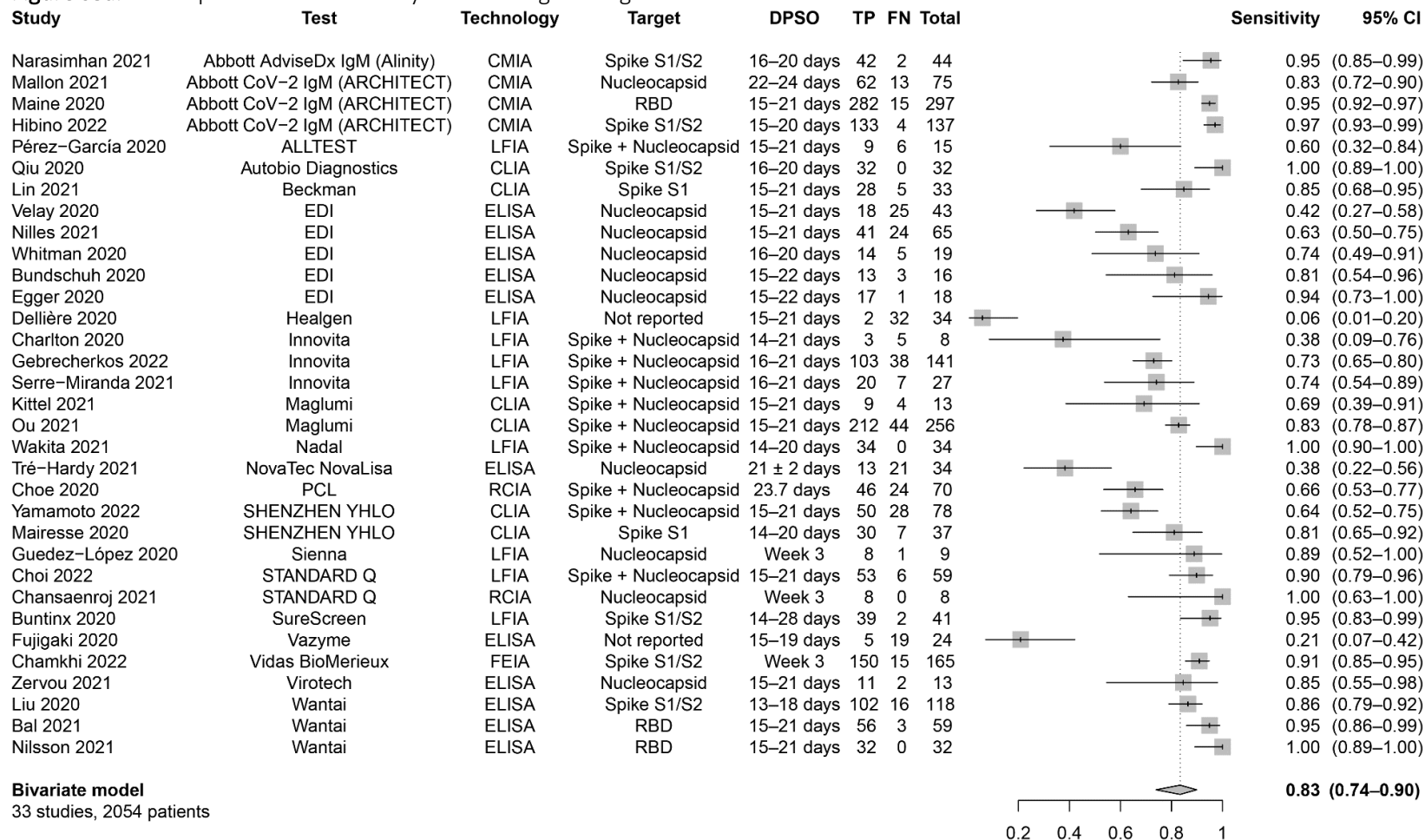
Figure s7b. Forest plot for the specificity of week 2 IgM or IgG combination tests using NAAT as reference standard



Supplement C

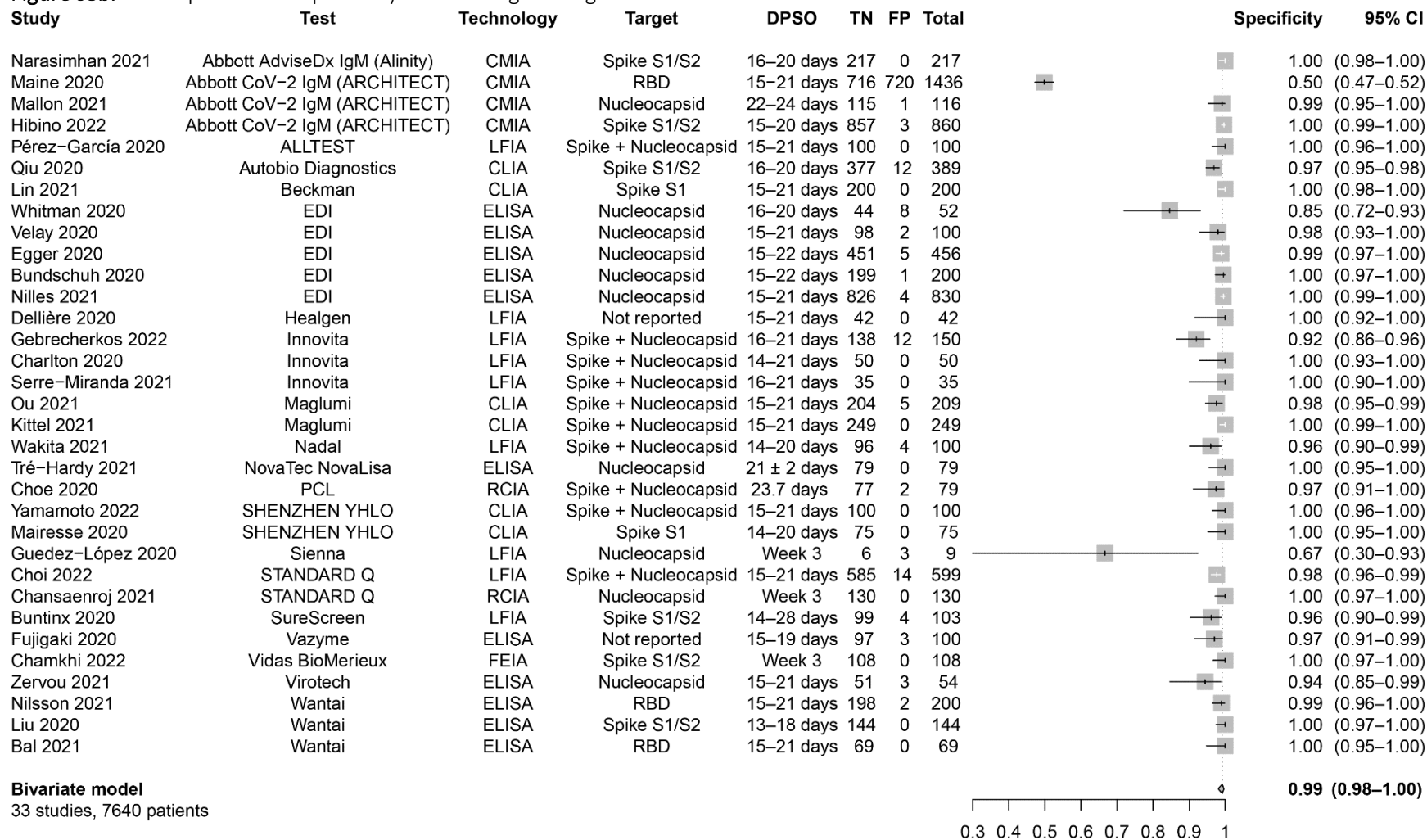
Recommendation: When evidence of previous SARS-CoV-2 infection is desired, the IDSA panel suggests for using IgG, IgG/IgM, or total antibodies and against using IgM to detect evidence of past SARS-CoV-2 infection (conditional recommendation, low certainty of evidence).

Figure s8a. Forest plot for the sensitivity of week 3 IgM using NAAT as reference standard



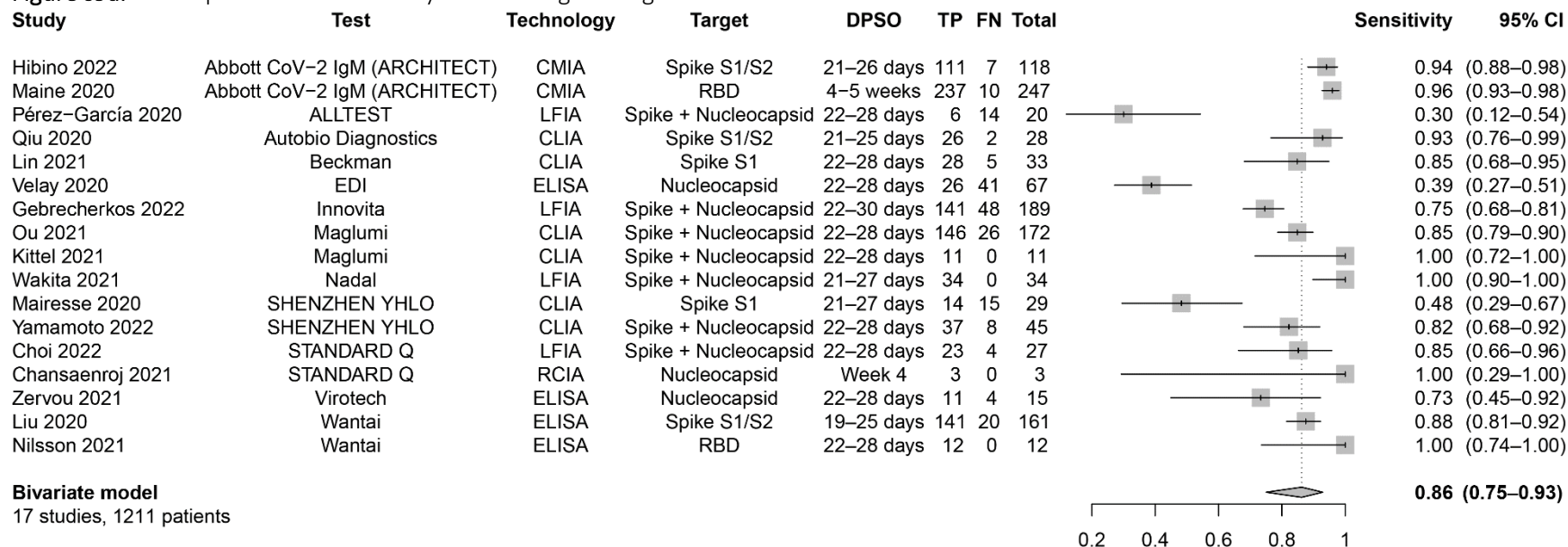
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Figure s8b. Forest plot for the specificity of week 3 IgM using NAAT as reference standard



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Figure s9a. Forest plot for the sensitivity of week 4 IgM using NAAT as reference standard



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Figure s9b. Forest plot for the specificity of week 4 IgM using NAAT as reference standard

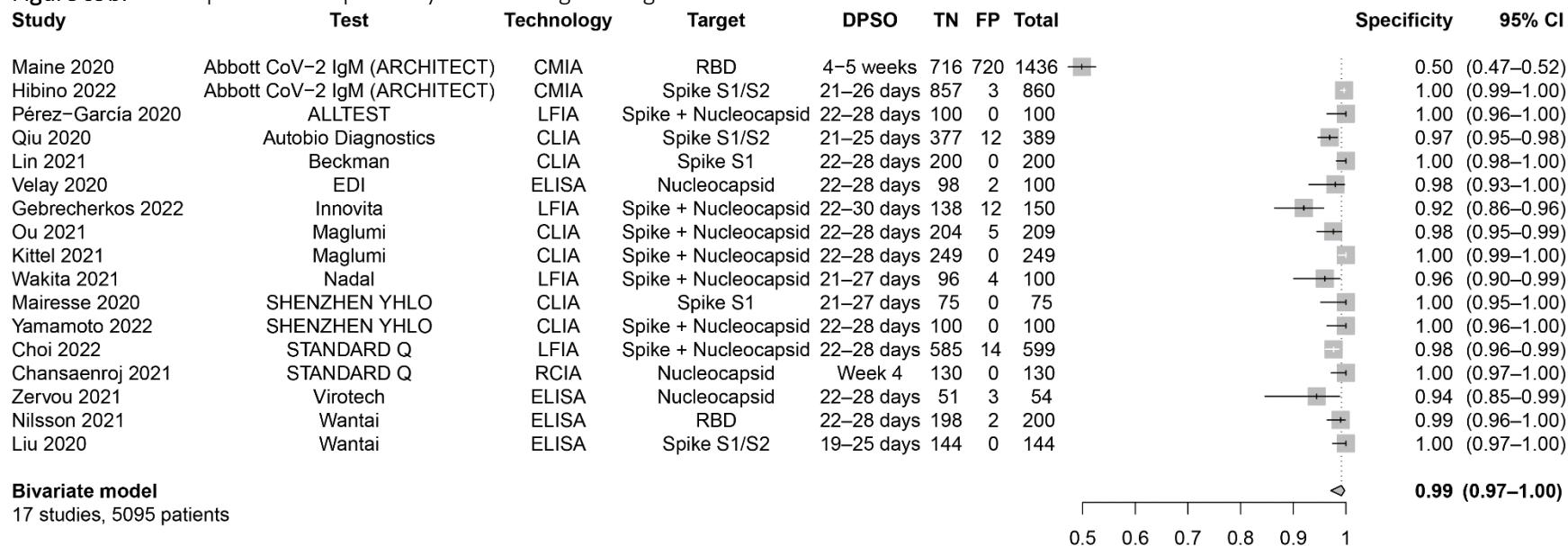


Figure s10a. Forest plot for the sensitivity of week 5 IgM using NAAT as reference standard

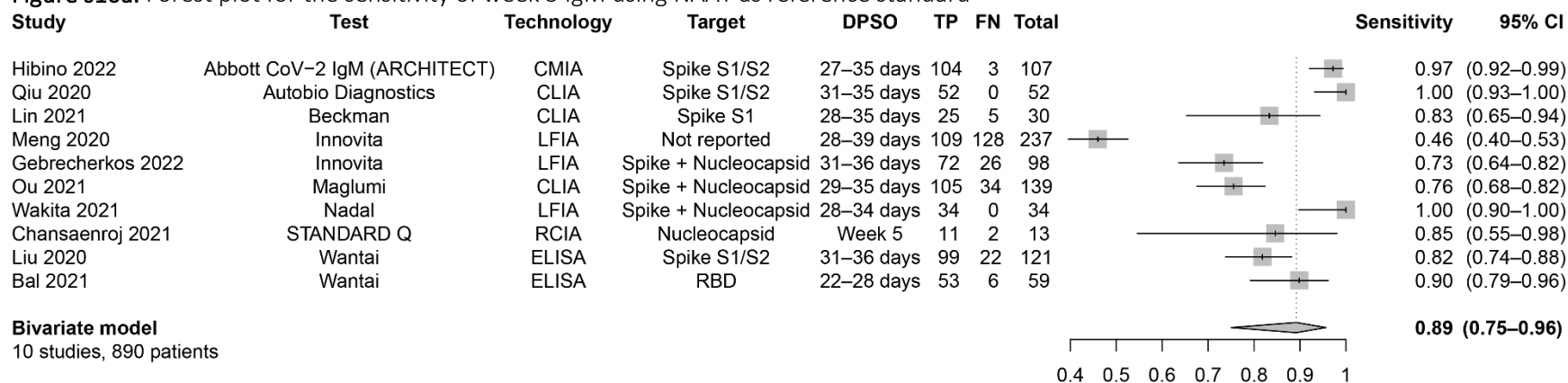


Figure s10b. Forest plot for the specificity of week 5 IgM using NAAT as reference standard

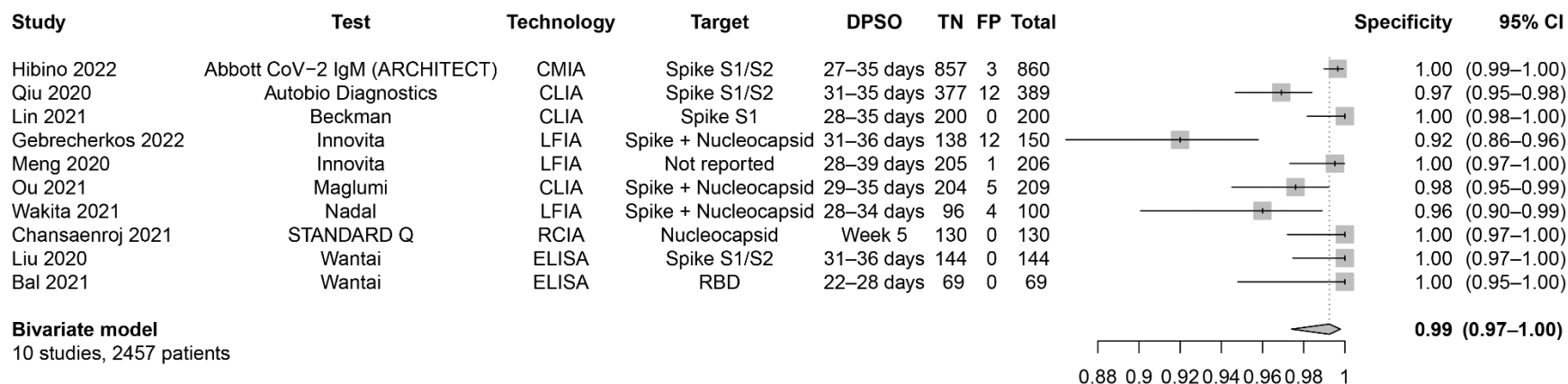
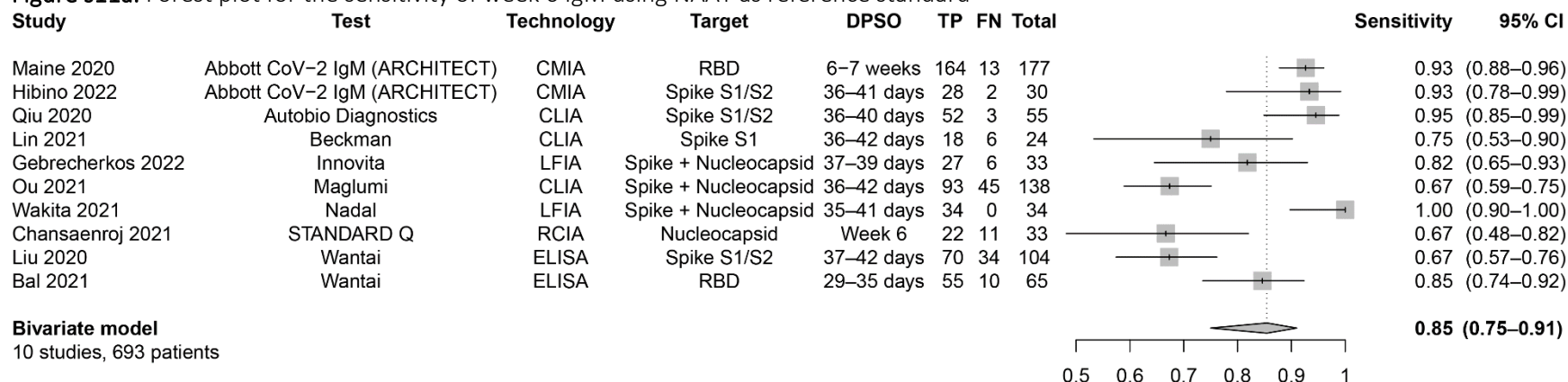


Figure s11a. Forest plot for the sensitivity of week 6 IgM using NAAT as reference standard



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Figure s11b. Forest plot for the specificity of week 6 IgM using NAAT as reference standard

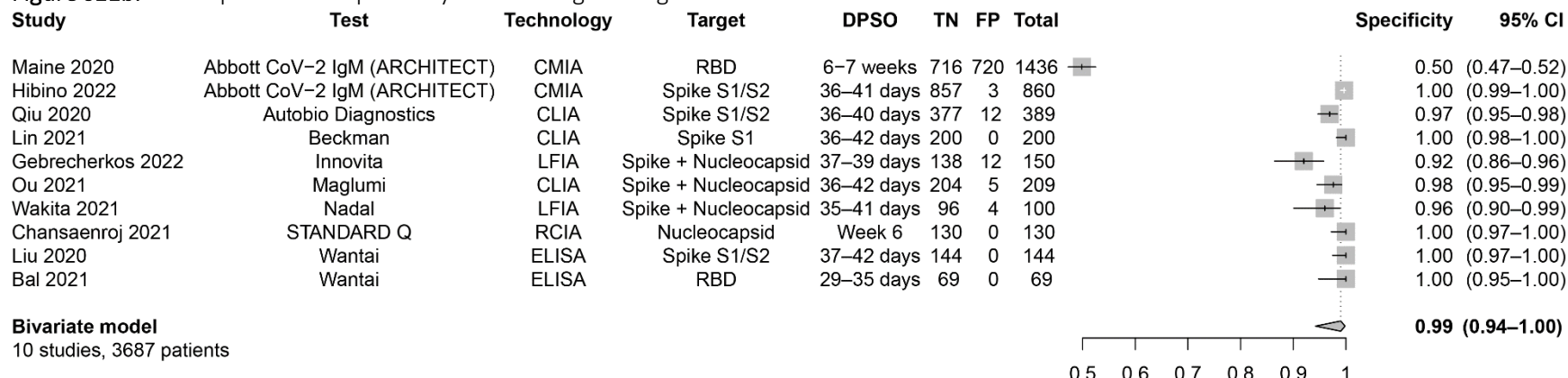


Figure s12a. Forest plot for the sensitivity of week 7 IgM using NAAT as reference standard

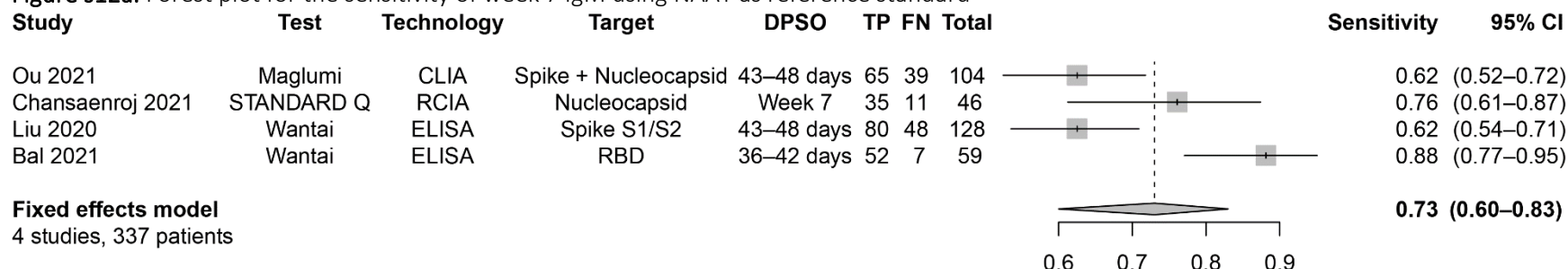
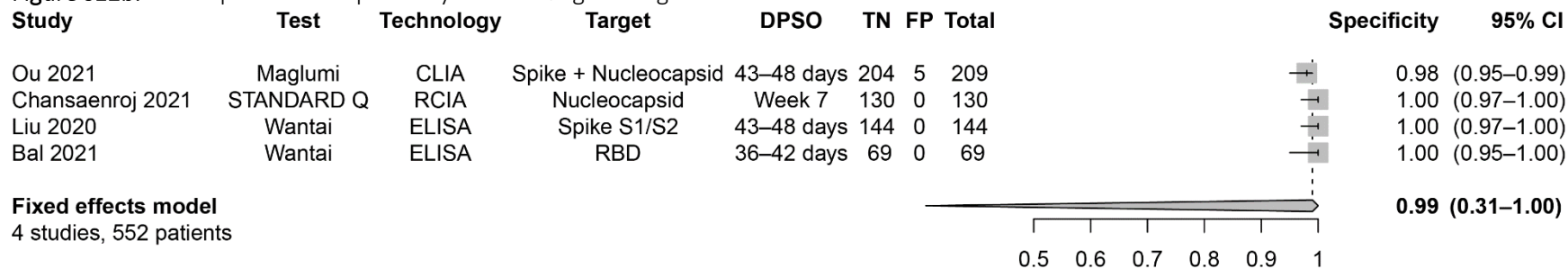


Figure s12b. Forest plot for the specificity of week 7 IgM using NAAT as reference standard



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Figure s13a. Forest plot for the sensitivity of week 8 IgM using NAAT as reference standard

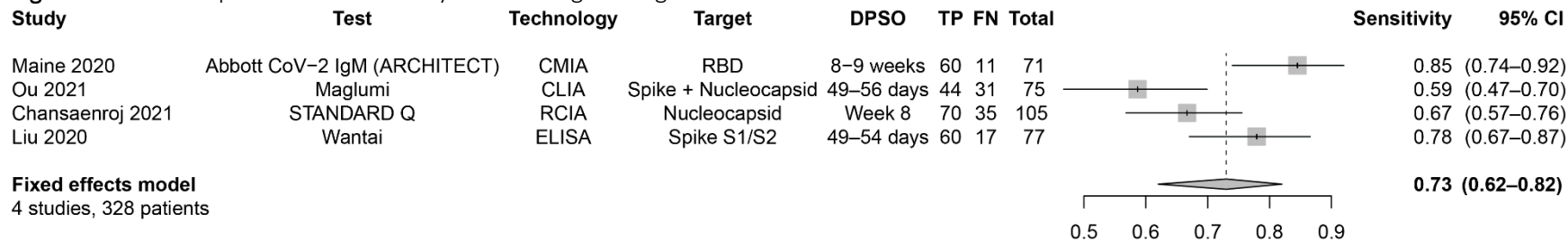
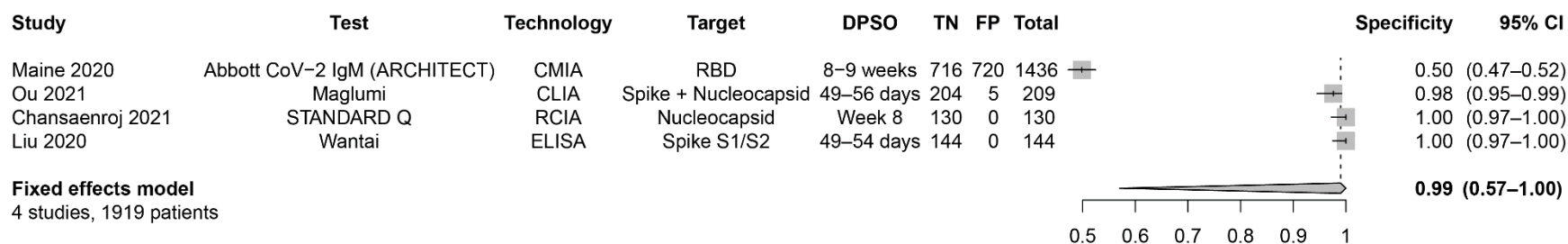
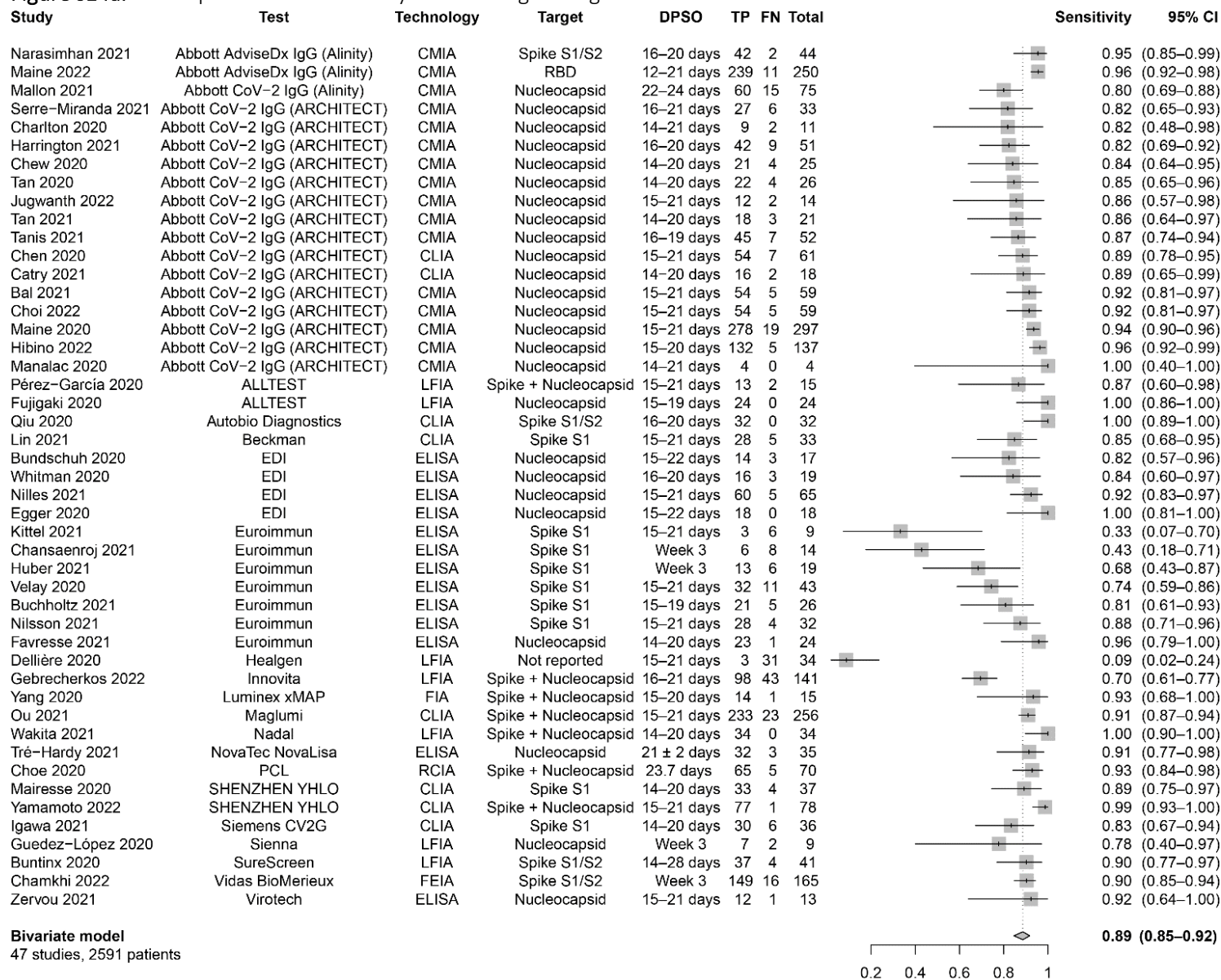


Figure s13b. Forest plot for the specificity of week 8 IgM using NAAT as reference standard



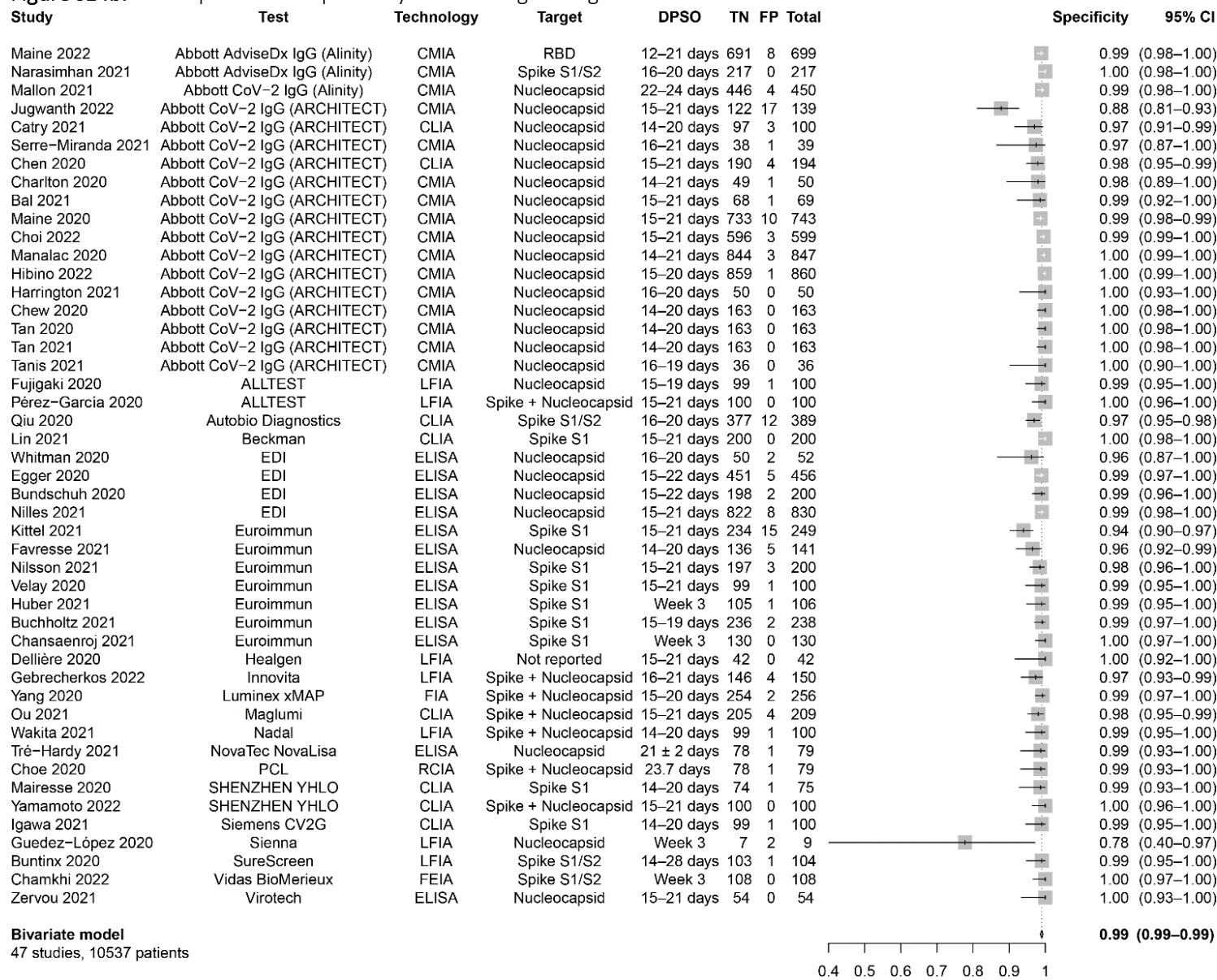
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Figure s14a. Forest plot for the sensitivity of week 3 IgG using NAAT as reference standard



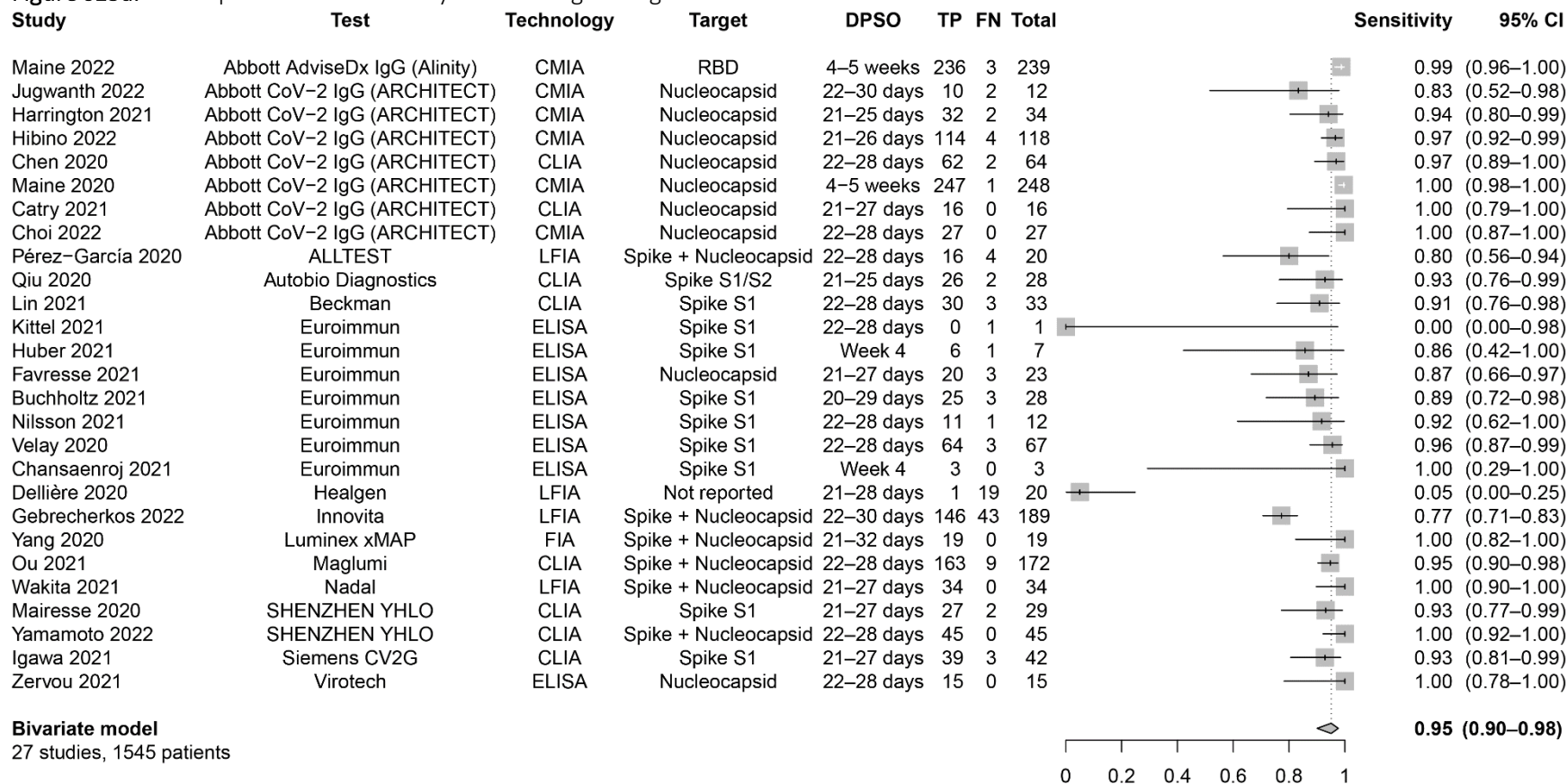
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Figure s14b. Forest plot for the specificity of week 3 IgG using NAAT as reference standard



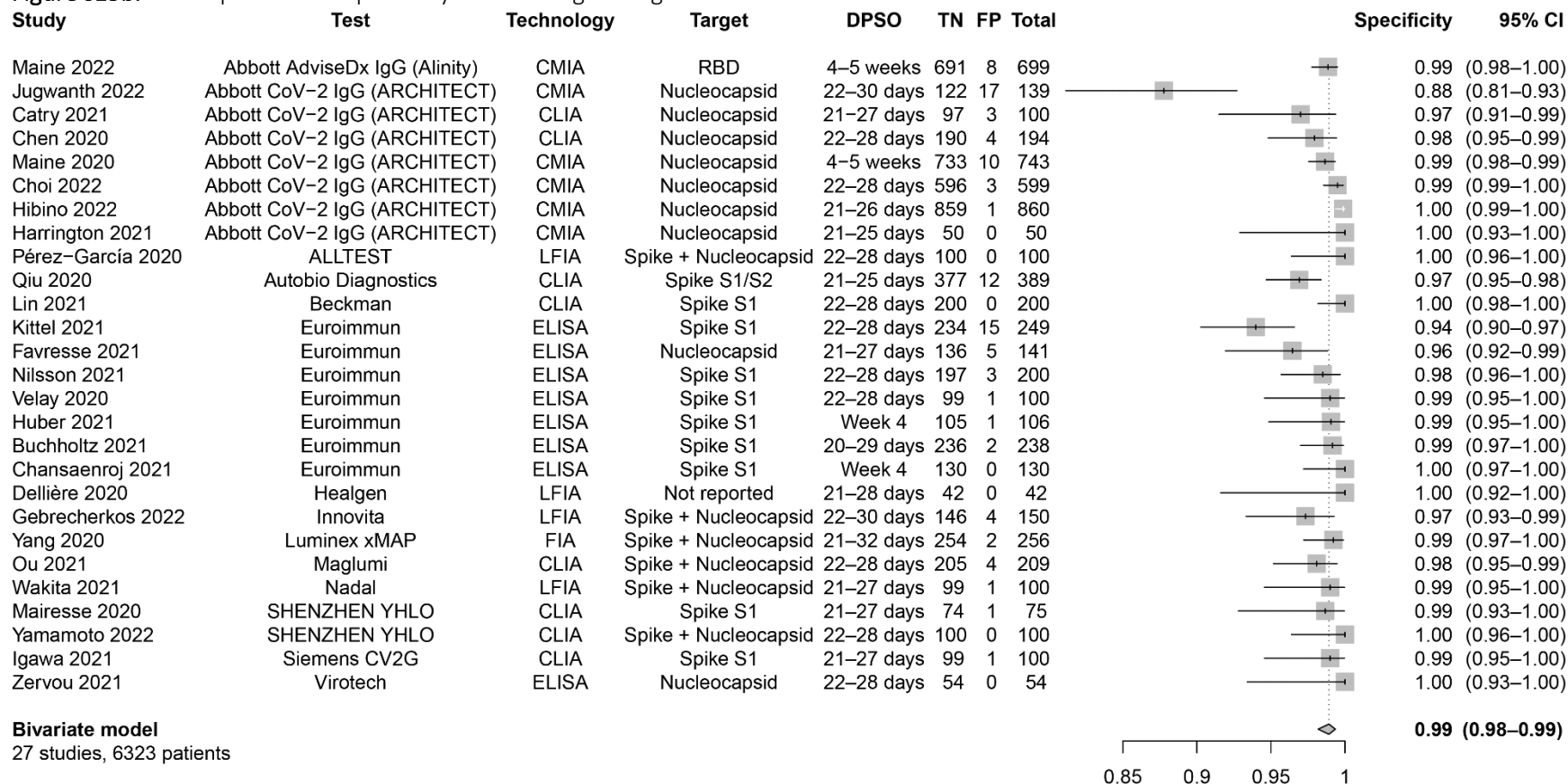
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Figure s15a. Forest plot for the sensitivity of week 4 IgG using NAAT as reference standard



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Figure s15b. Forest plot for the specificity of week 4 IgG using NAAT as reference standard



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Figure s16a. Forest plot for the sensitivity of week 5 IgG using NAAT as reference standard

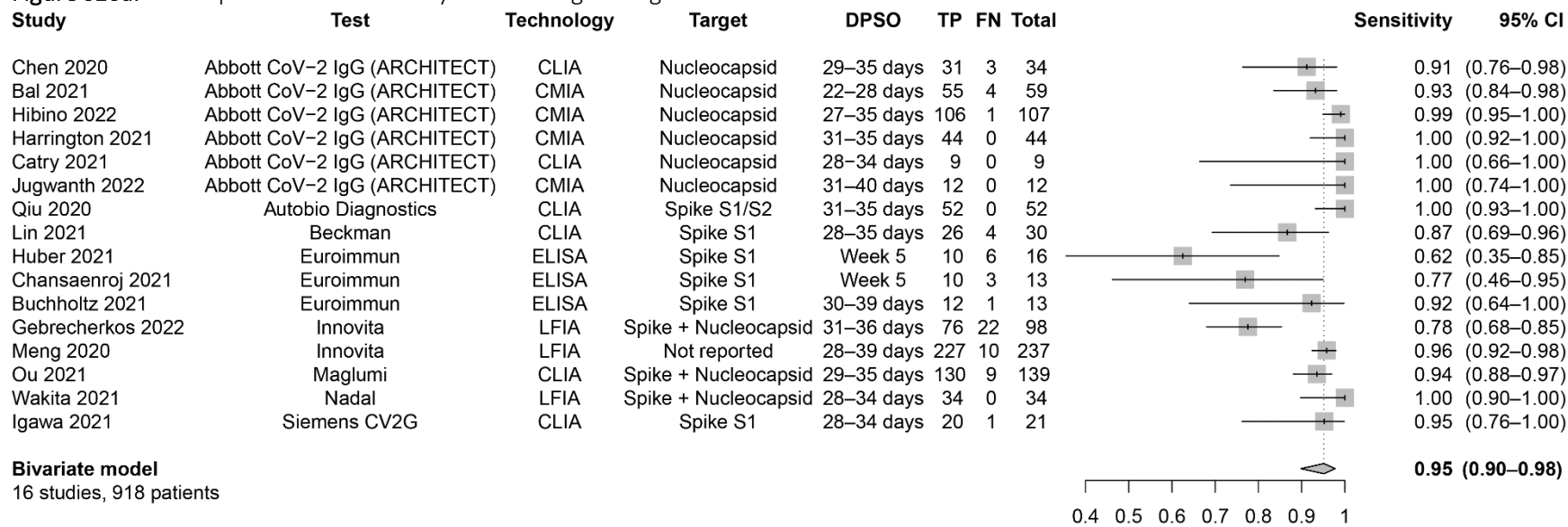


Figure s16b. Forest plot for the specificity of week 5 IgG using NAAT as reference standard

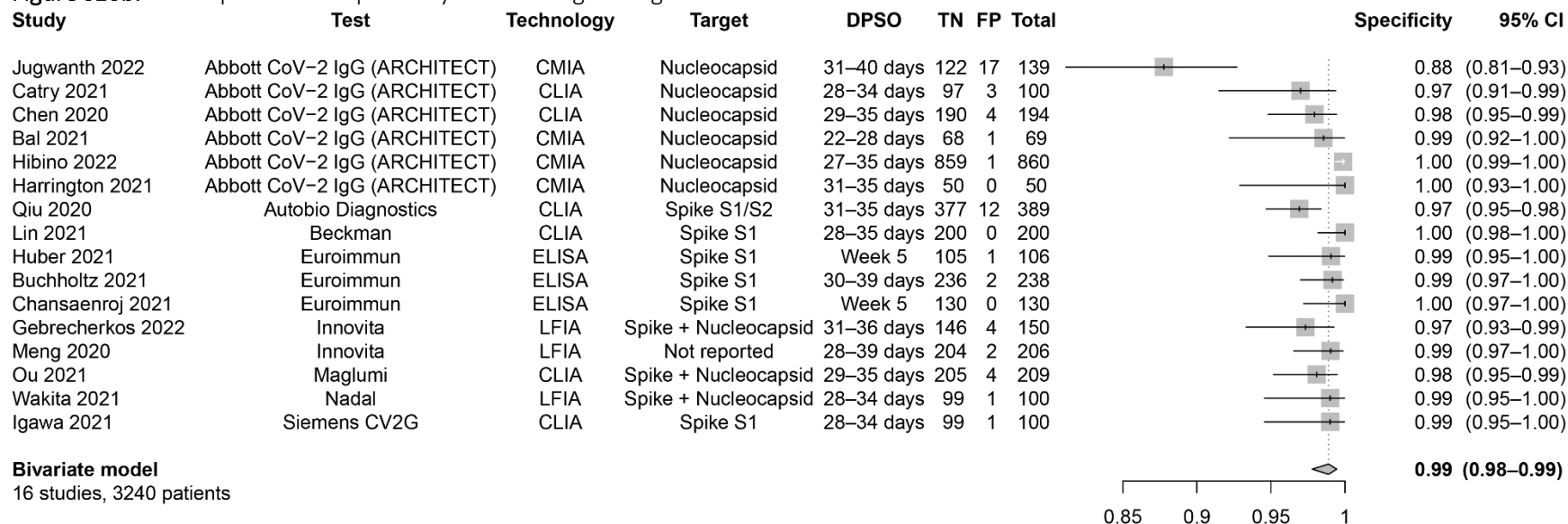
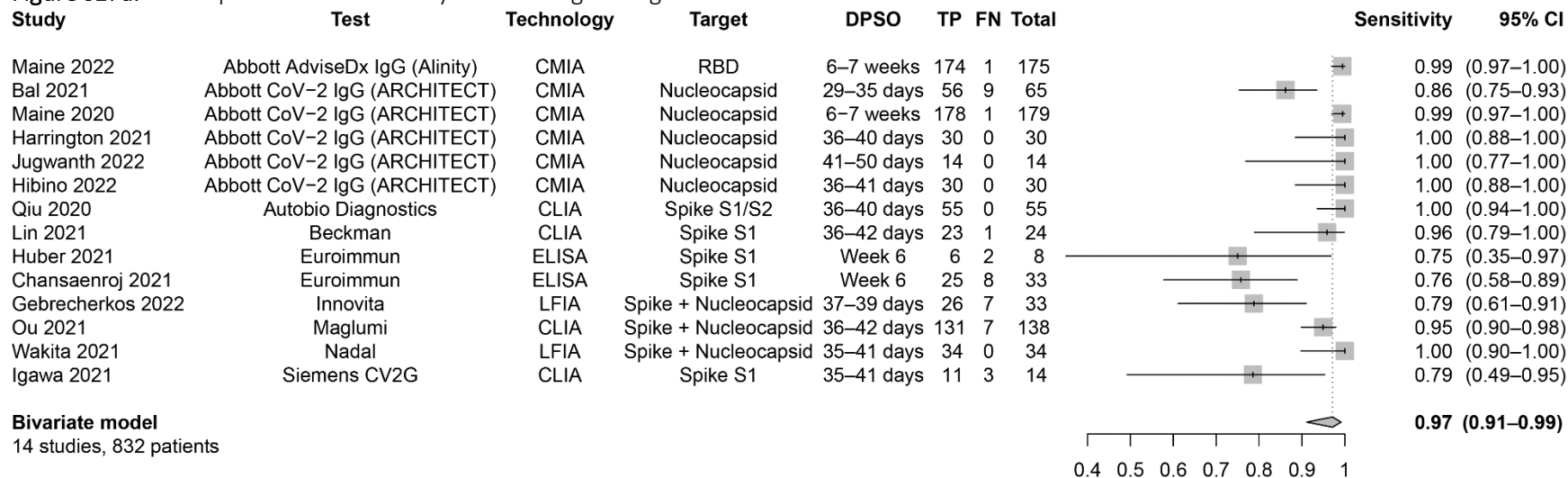


Figure s17a. Forest plot for the sensitivity of week 6 IgG using NAAT as reference standard



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Figure s17b. Forest plot for the specificity of week 6 IgG using NAAT as reference standard

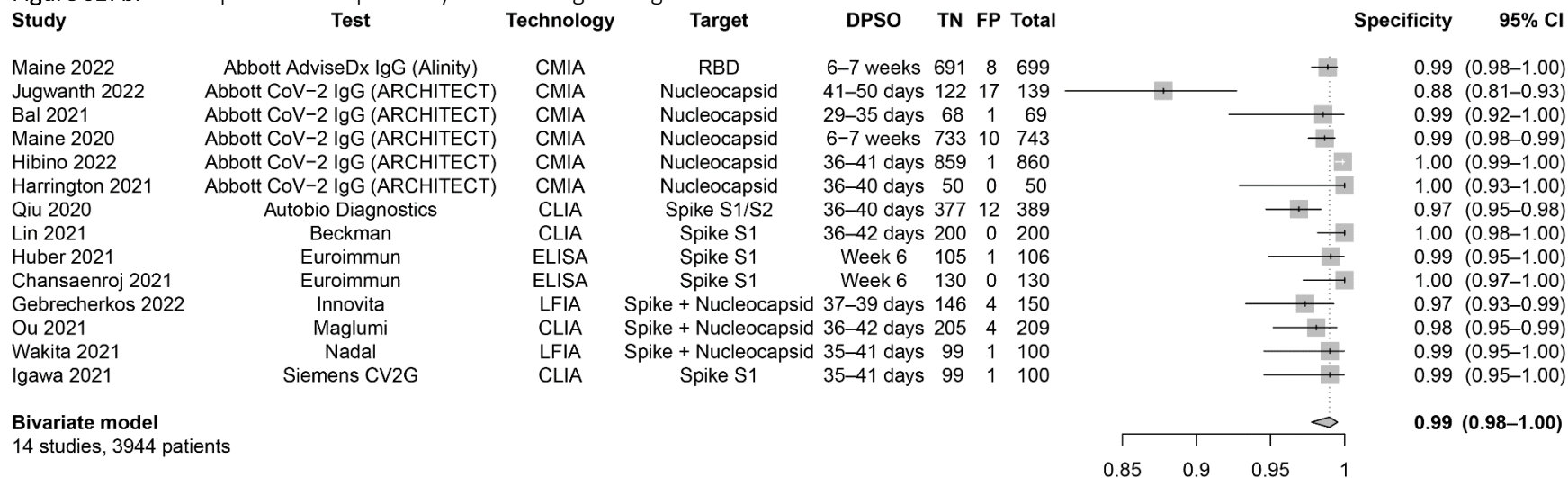
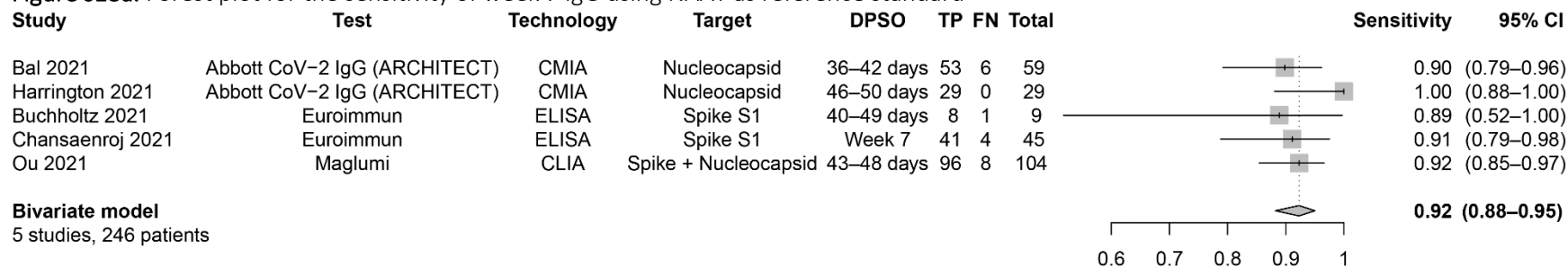


Figure s18a. Forest plot for the sensitivity of week 7 IgG using NAAT as reference standard



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Figure s18b. Forest plot for the specificity of week 7 IgG using NAAT as reference standard

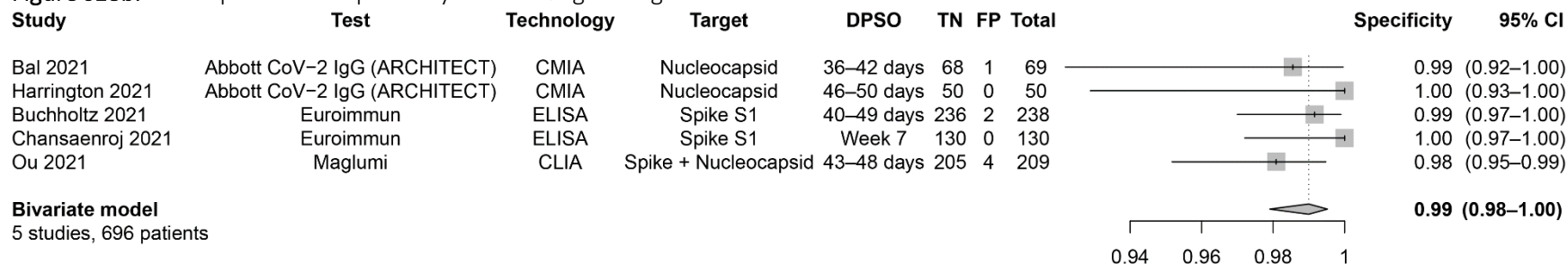


Figure s19a. Forest plot for the sensitivity of week 8 IgG using NAAT as reference standard

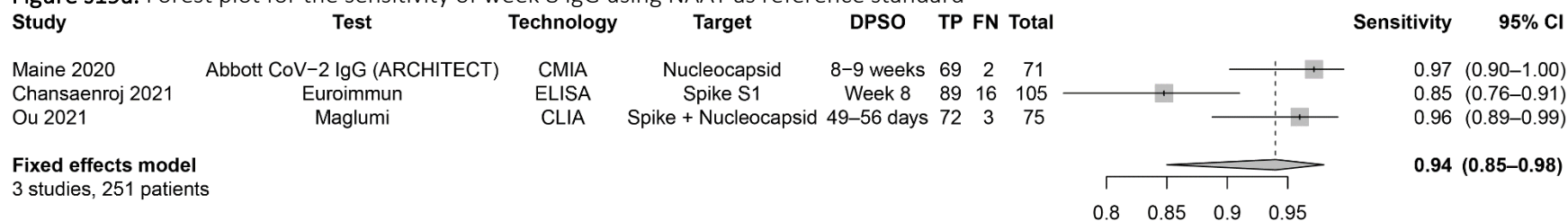
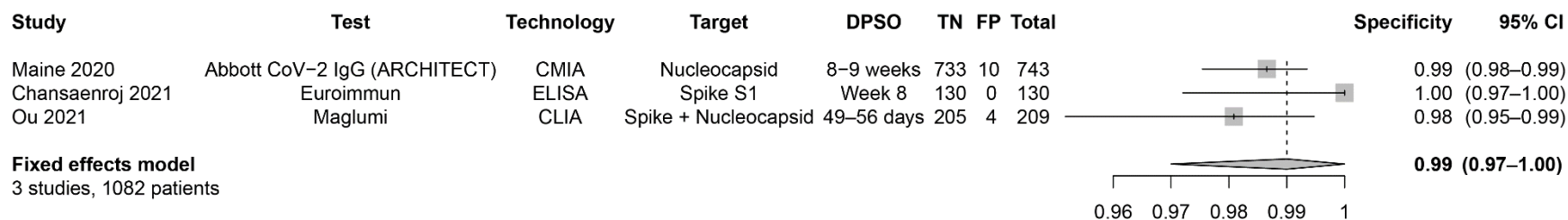
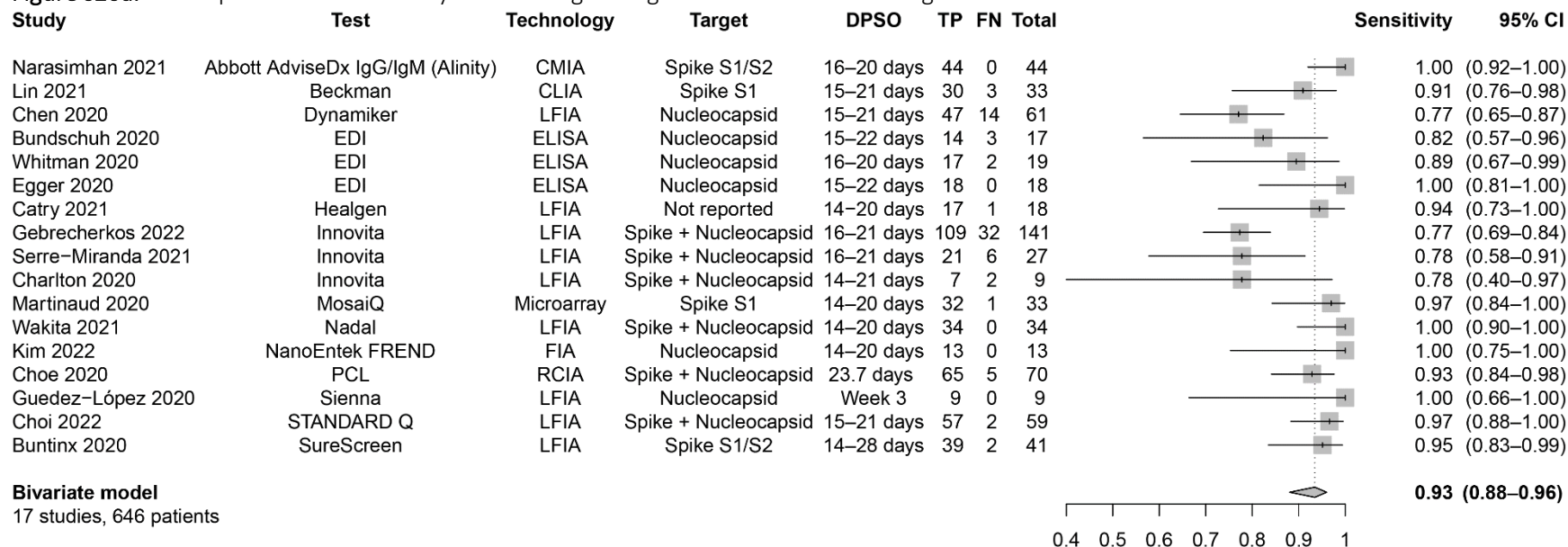


Figure s19b. Forest plot for the specificity of week 8 IgG using NAAT as reference standard



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Figure s20a. Forest plot for the sensitivity of week 3 IgM or IgG combination tests using NAAT as reference standard



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Figure s20b. Forest plot for the specificity of week 3 IgM or IgG combination tests using NAAT as reference standard

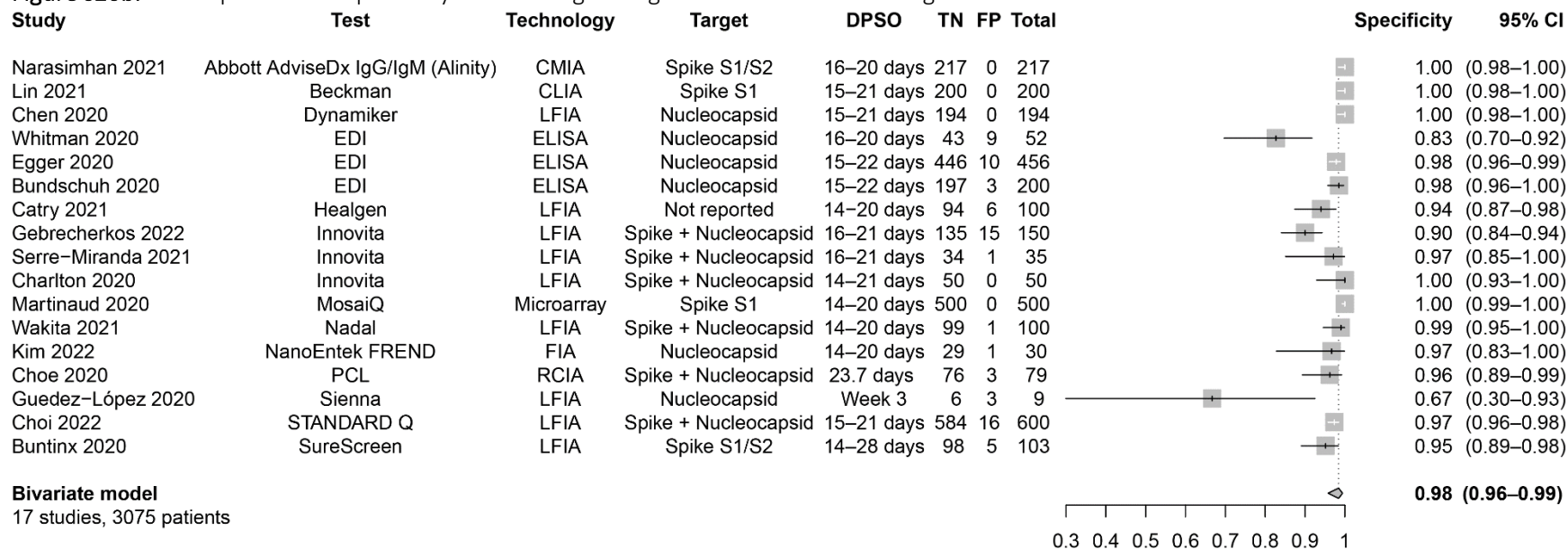


Figure s21a. Forest plot for the sensitivity of week 4 IgM or IgG combination tests using NAAT as reference standard

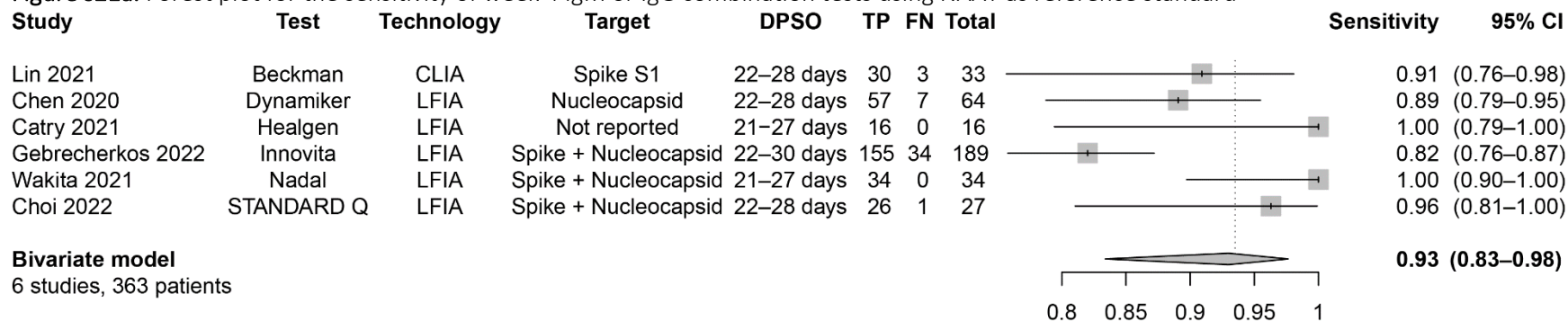


Figure s21b. Forest plot for the specificity of week 4 IgM or IgG combination tests using NAAT as reference standard

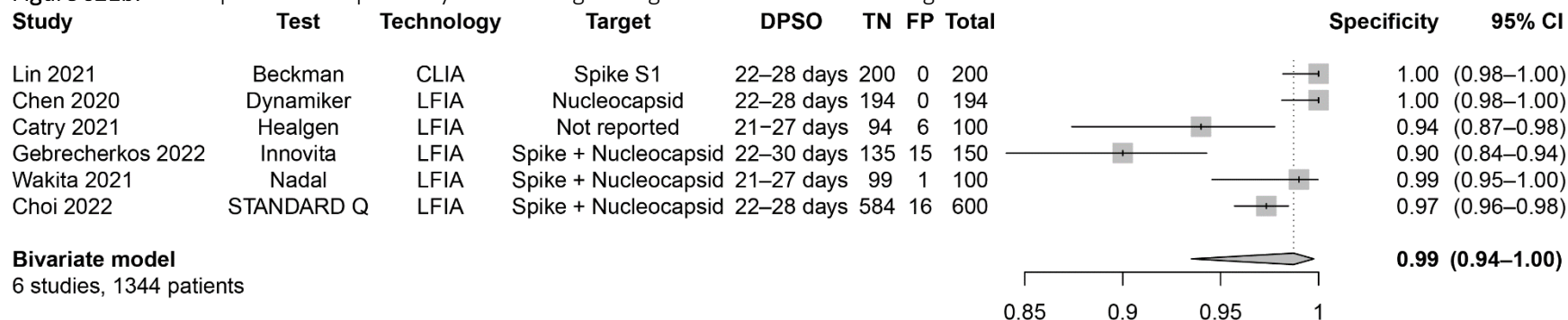


Figure s22a. Forest plot for the sensitivity of week 5 IgM or IgG combination tests using NAAT as reference standard

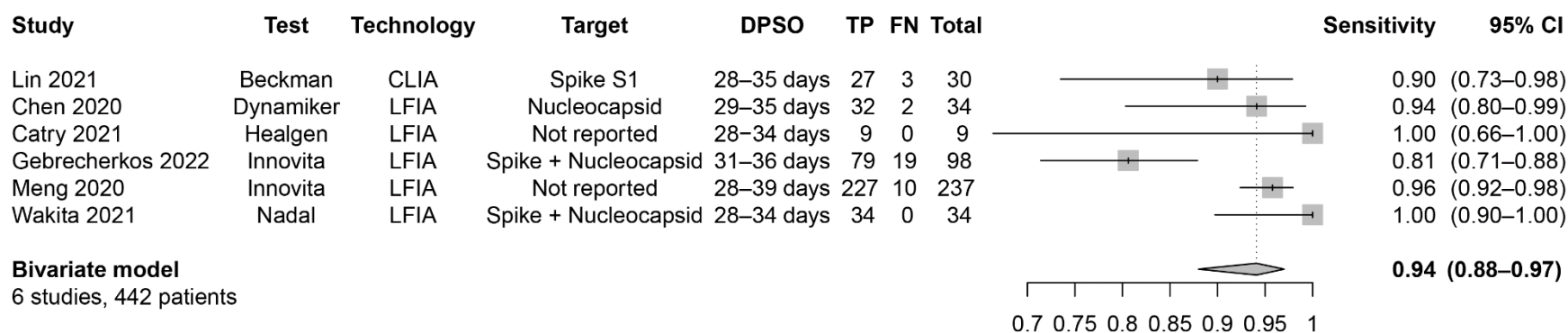


Figure s22b. Forest plot for the specificity of week 5 IgM or IgG combination tests using NAAT as reference standard

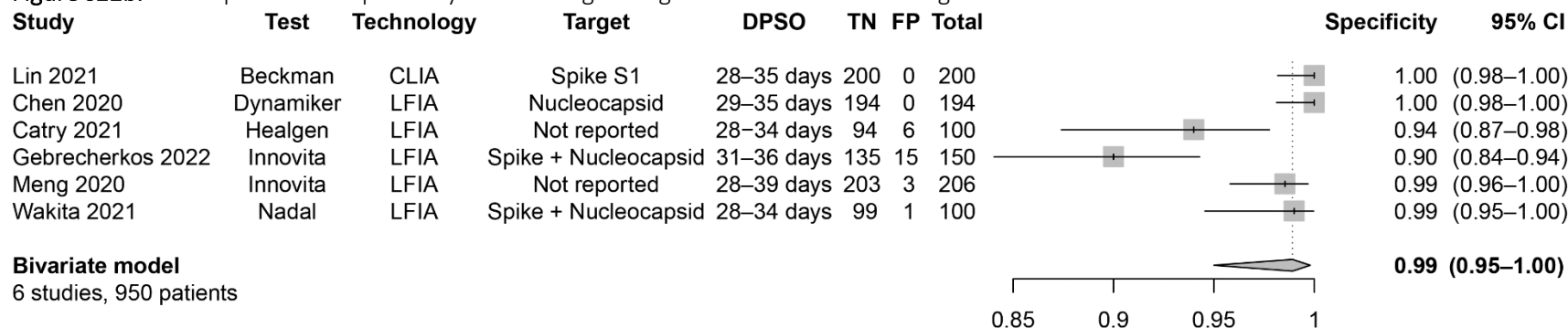


Figure s23a. Forest plot for the sensitivity of week 6 IgM or IgG combination tests using NAAT as reference standard

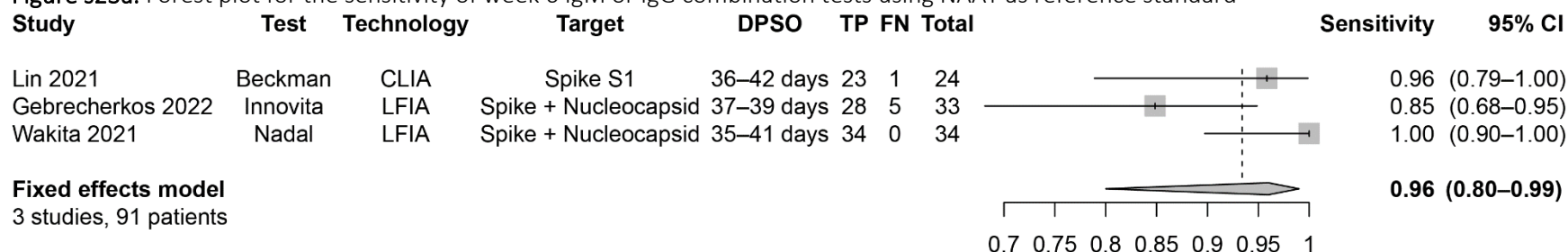


Figure s23b. Forest plot for the specificity of week 6 IgM or IgG combination tests using NAAT as reference standard

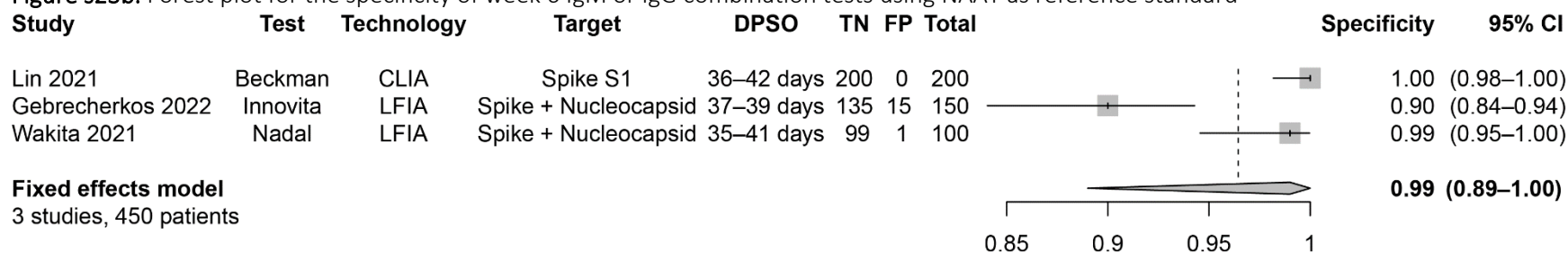


Figure s24a. Forest plot for the sensitivity of week 3 Total Antibodies using NAAT as reference standard

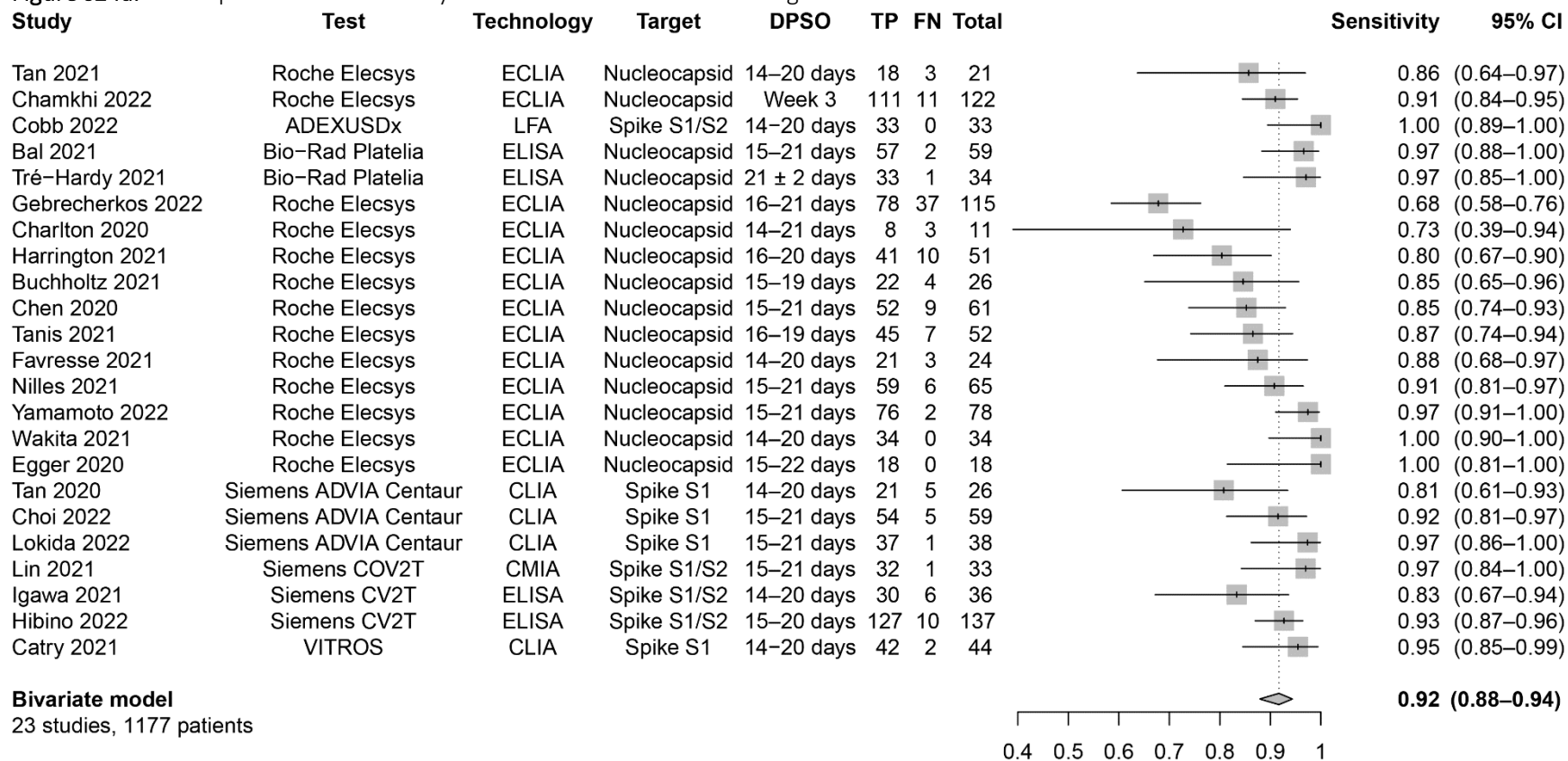
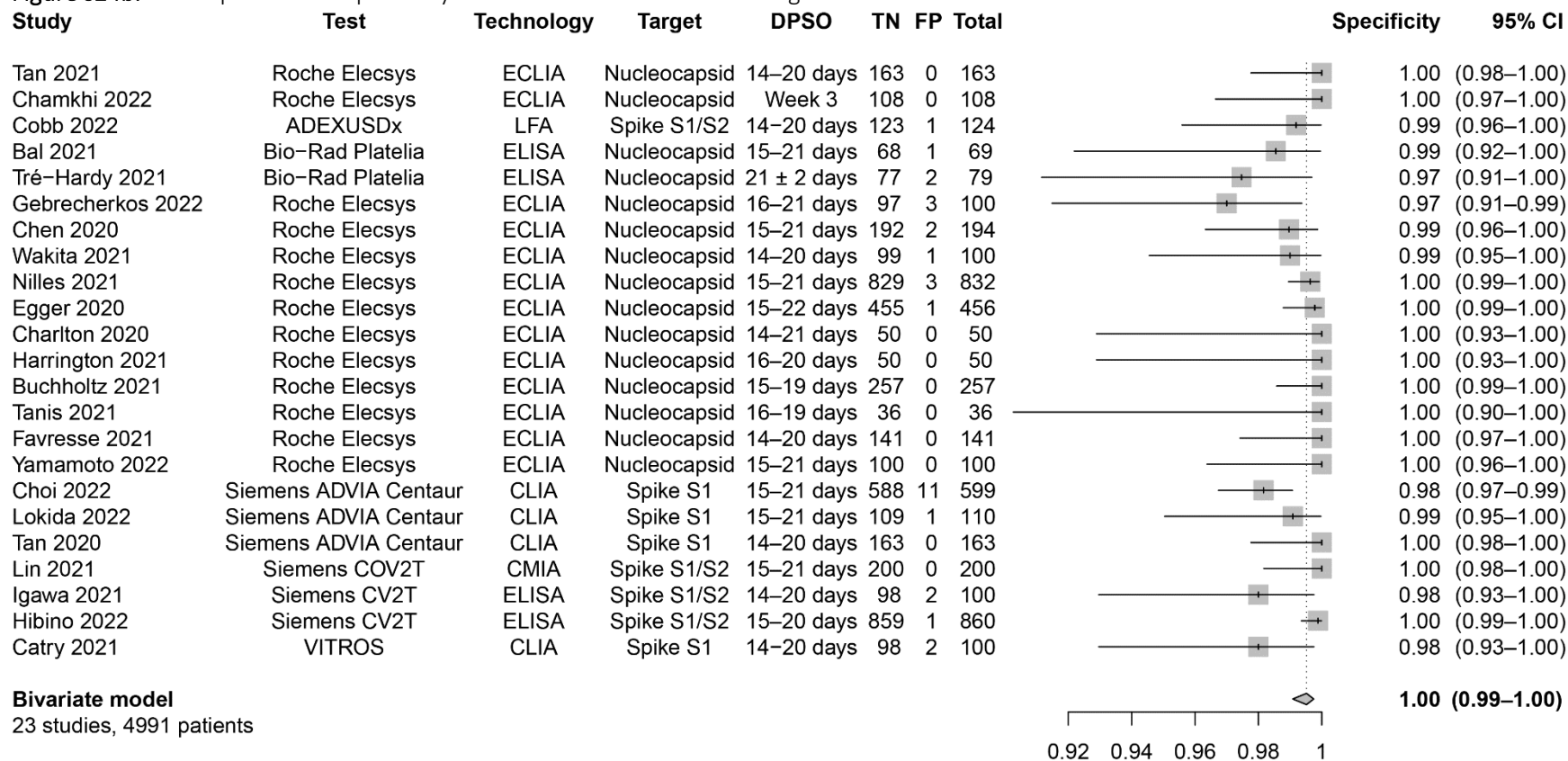


Figure s24b. Forest plot for the specificity of week 3 Total Antibodies using NAAT as reference standard



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Figure s25a. Forest plot for the sensitivity of week 4 Total Antibodies using NAAT as reference standard

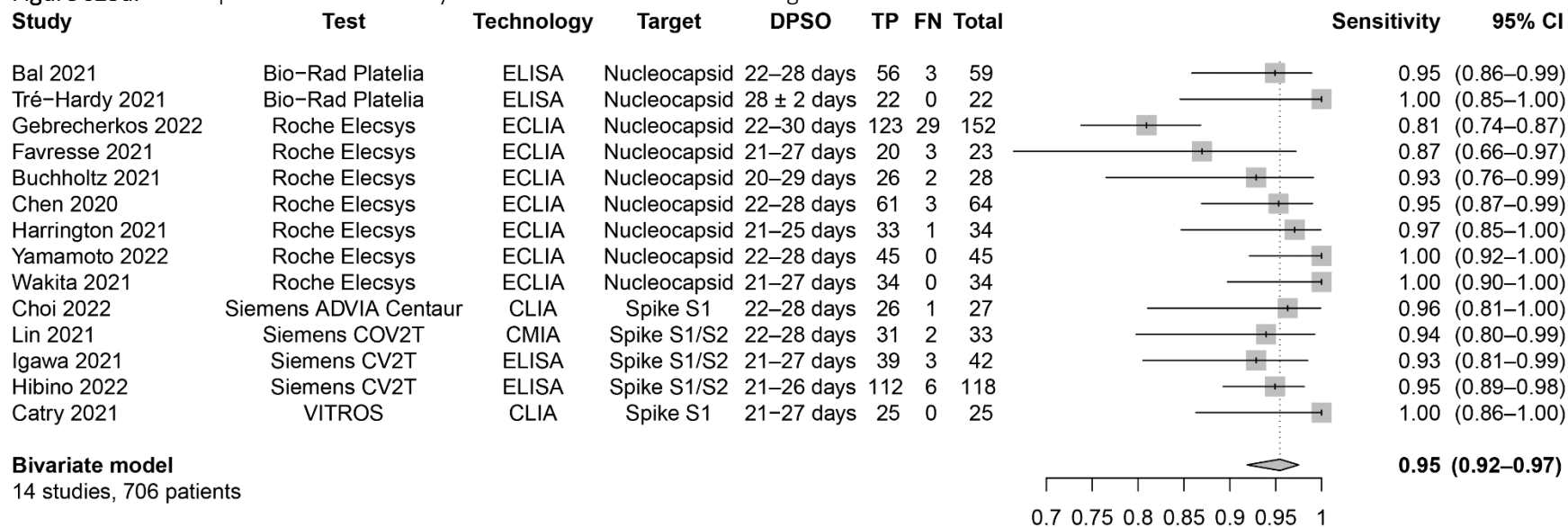


Figure s25b. Forest plot for the specificity of week 4 Total Antibodies using NAAT as reference standard

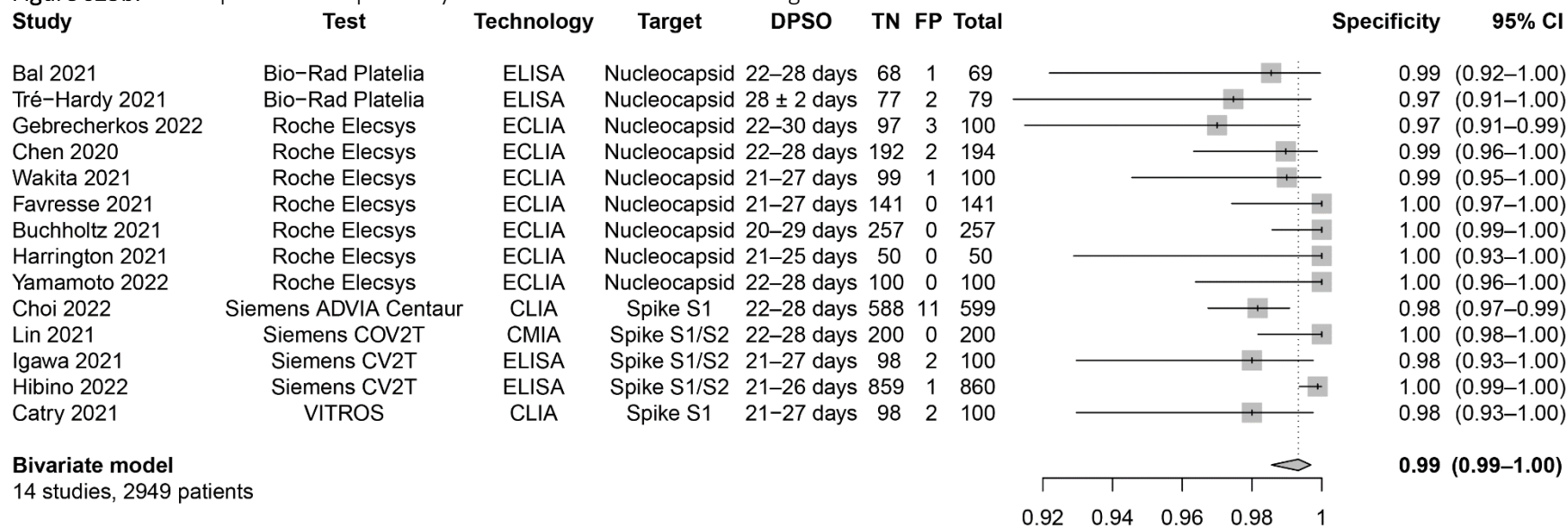


Figure s26a. Forest plot for the sensitivity of week 5 Total Antibodies using NAAT as reference standard

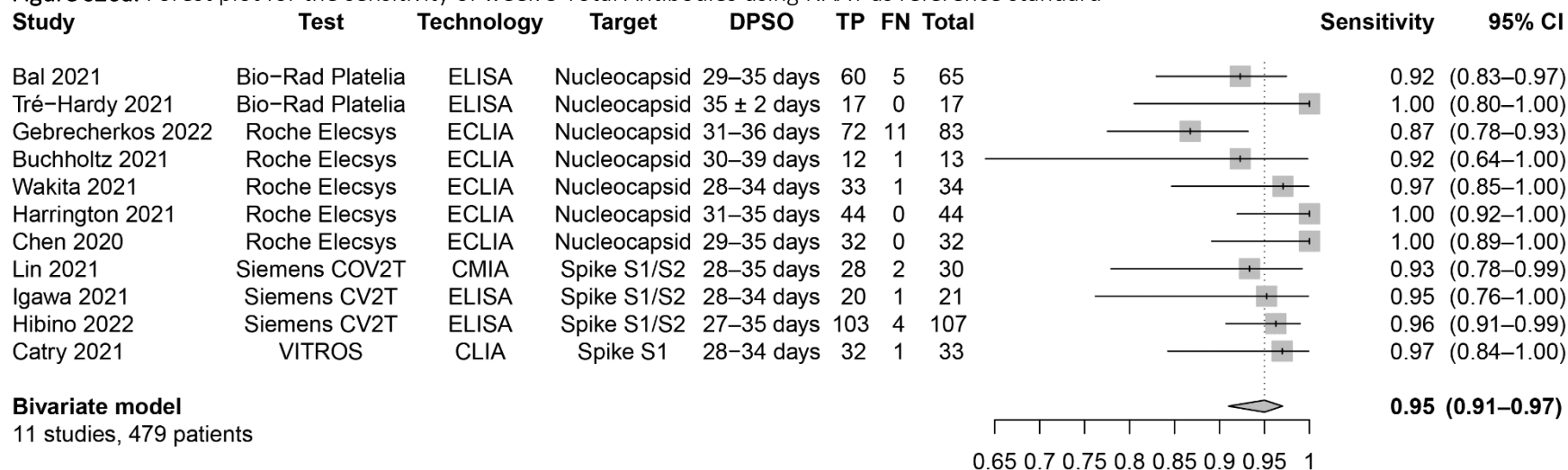


Figure s26b. Forest plot for the specificity of week 5 Total Antibodies using NAAT as reference standard

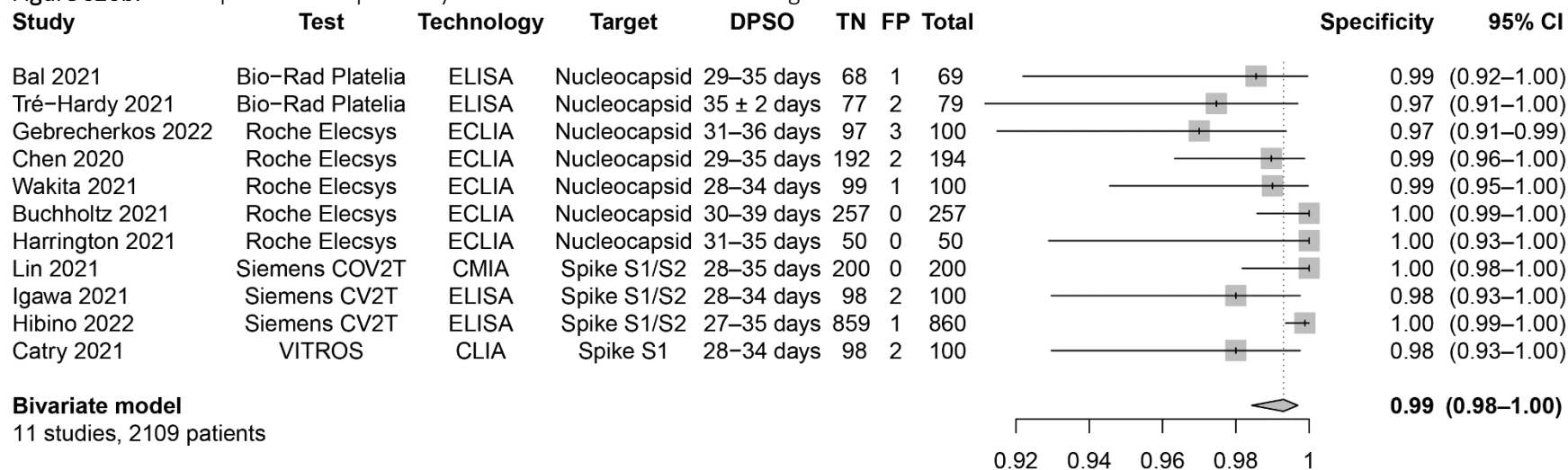


Figure s27a. Forest plot for the sensitivity of week 6 Total Antibodies using NAAT as reference standard

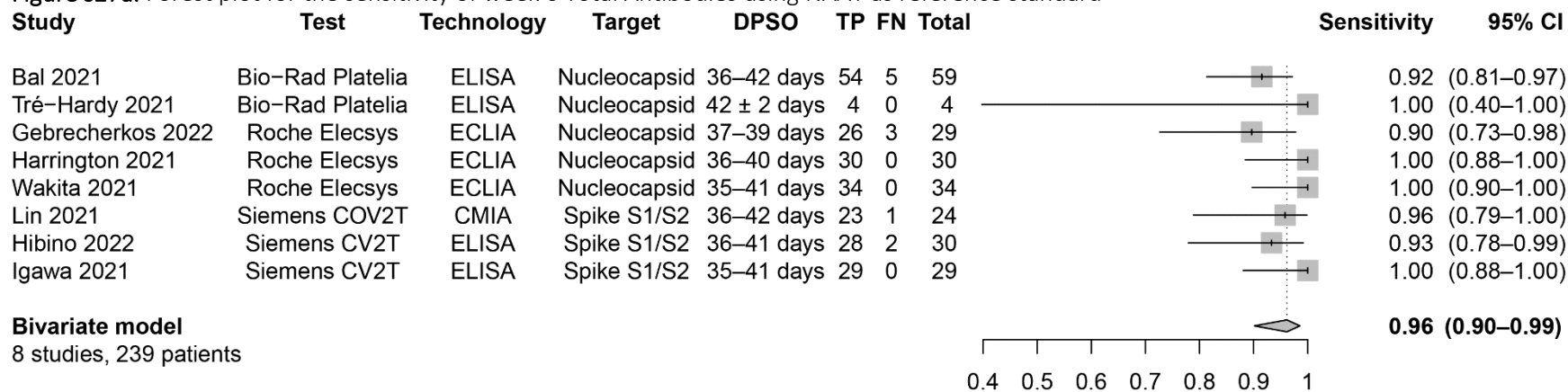


Figure s27b. Forest plot for the specificity of week 6 Total Antibodies using NAAT as reference standard

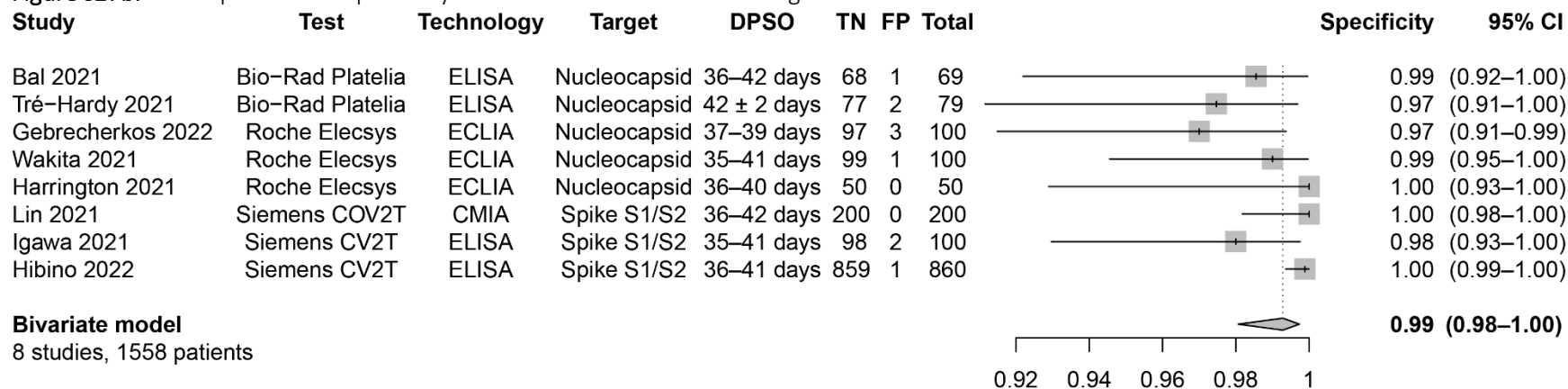


Figure s28a. Forest plot for the sensitivity of week 7 Total Antibodies using NAAT as reference standard

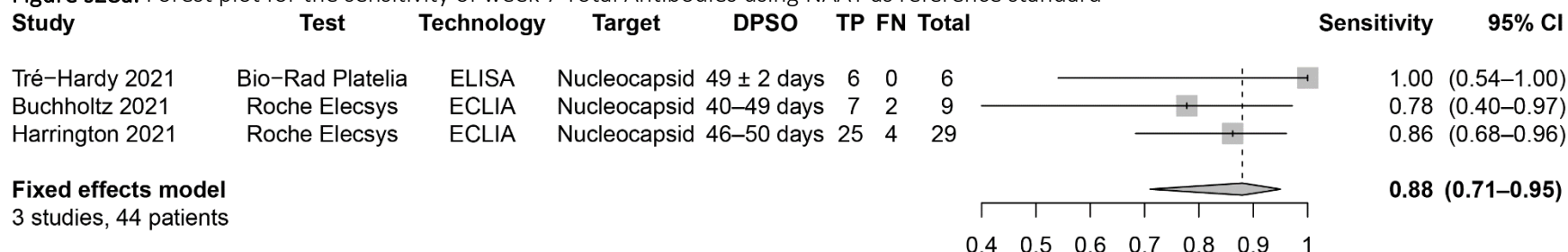
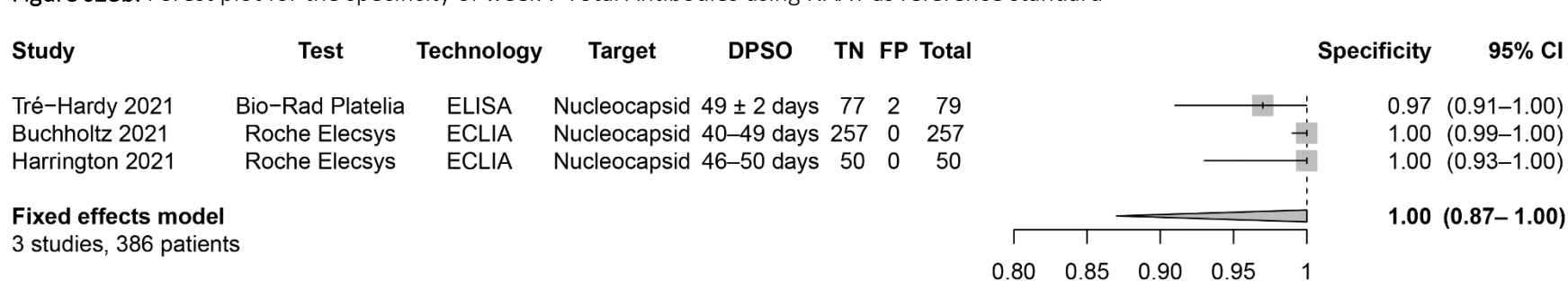


Figure s28b. Forest plot for the specificity of week 7 Total Antibodies using NAAT as reference standard



Supplement D

Recommendation : When evidence of previous SARS-CoV-2 infection is desired, the IDSA panel suggests using serologic assays that target nucleocapsid rather than spike to detect evidence of past SARS-CoV-2 infection (conditional recommendation, low certainty of evidence).

Figure s29a. Forest plot for the sensitivity of IgG assays targeting spike using NAAT as reference standard

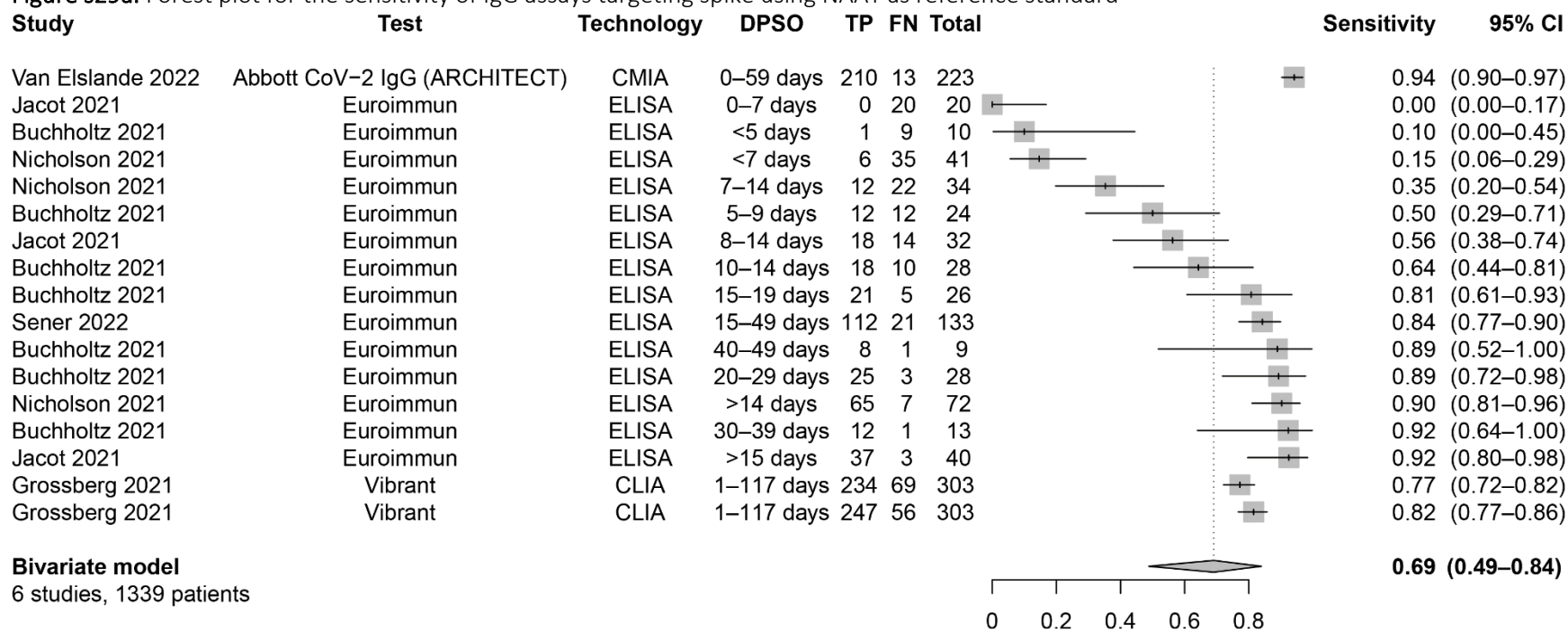


Figure s29b. Forest plot for the specificity of IgG assays targeting spike using NAAT as reference standard

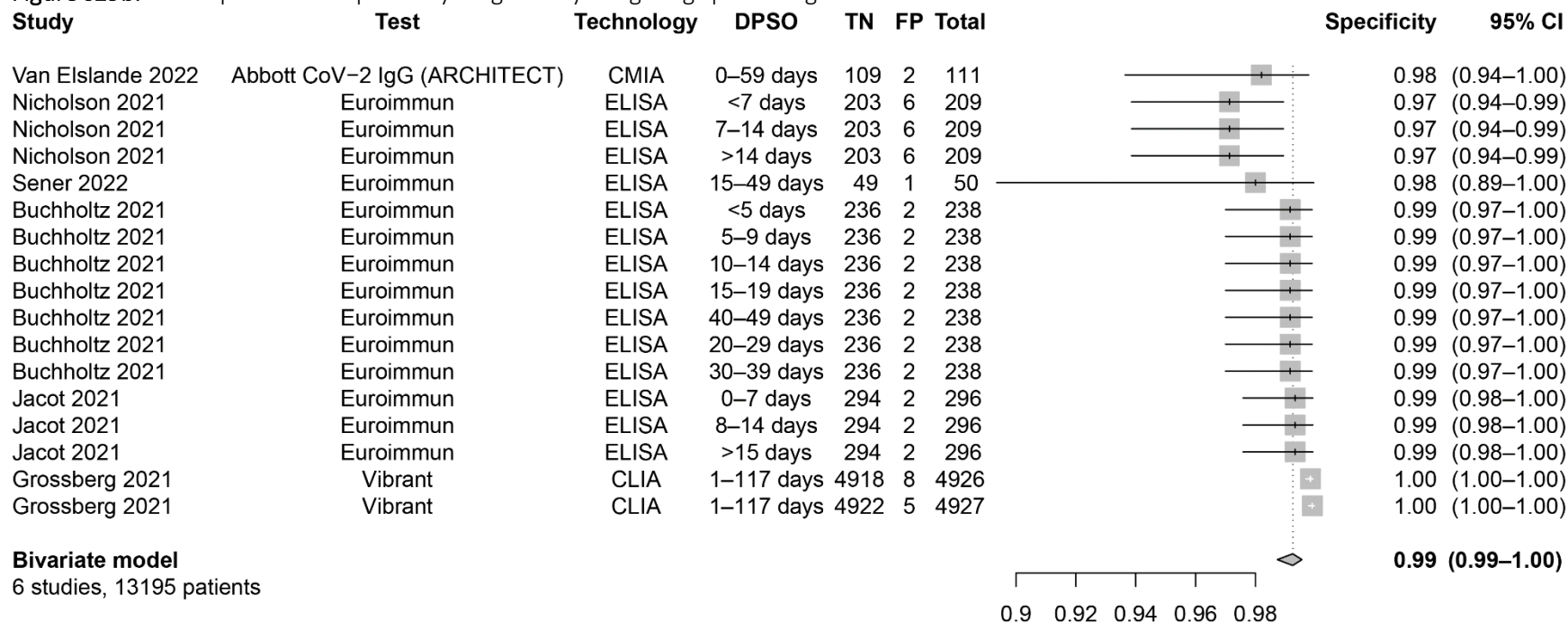


Figure s30a. Forest plot for the sensitivity of IgG assays targeting Nucleocapsid using NAAT as reference standard

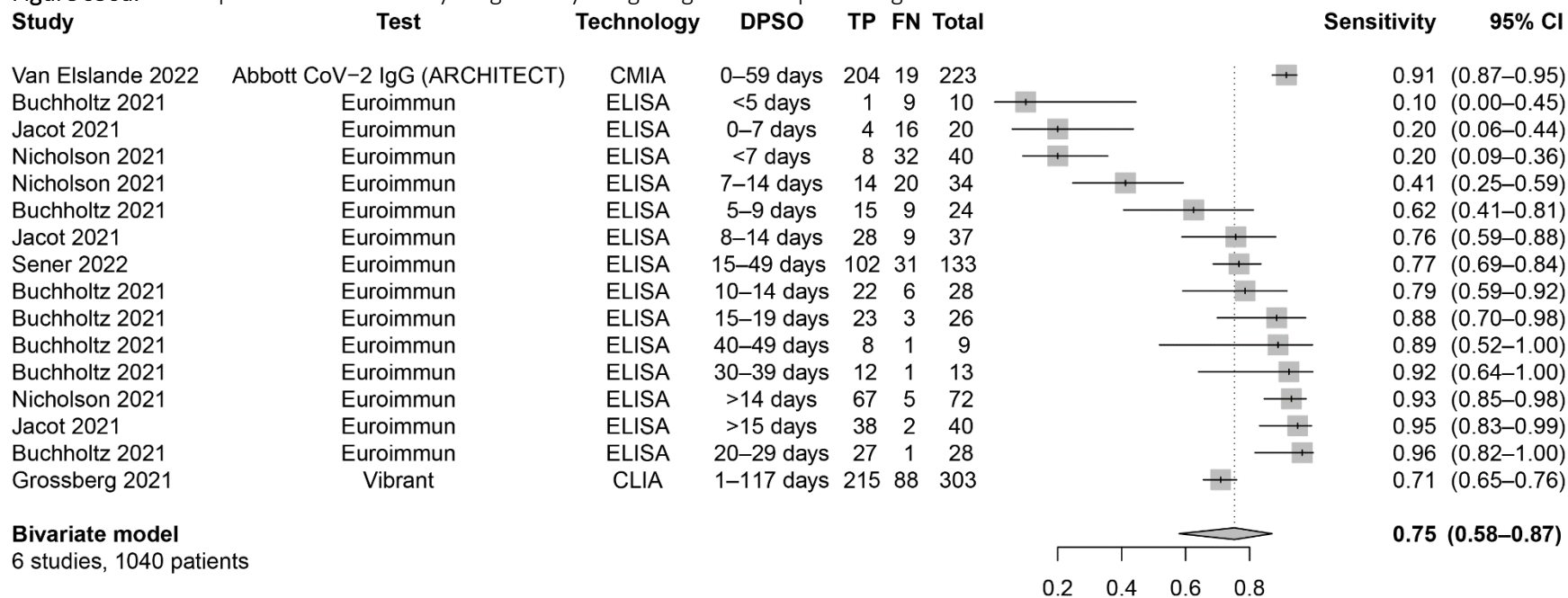
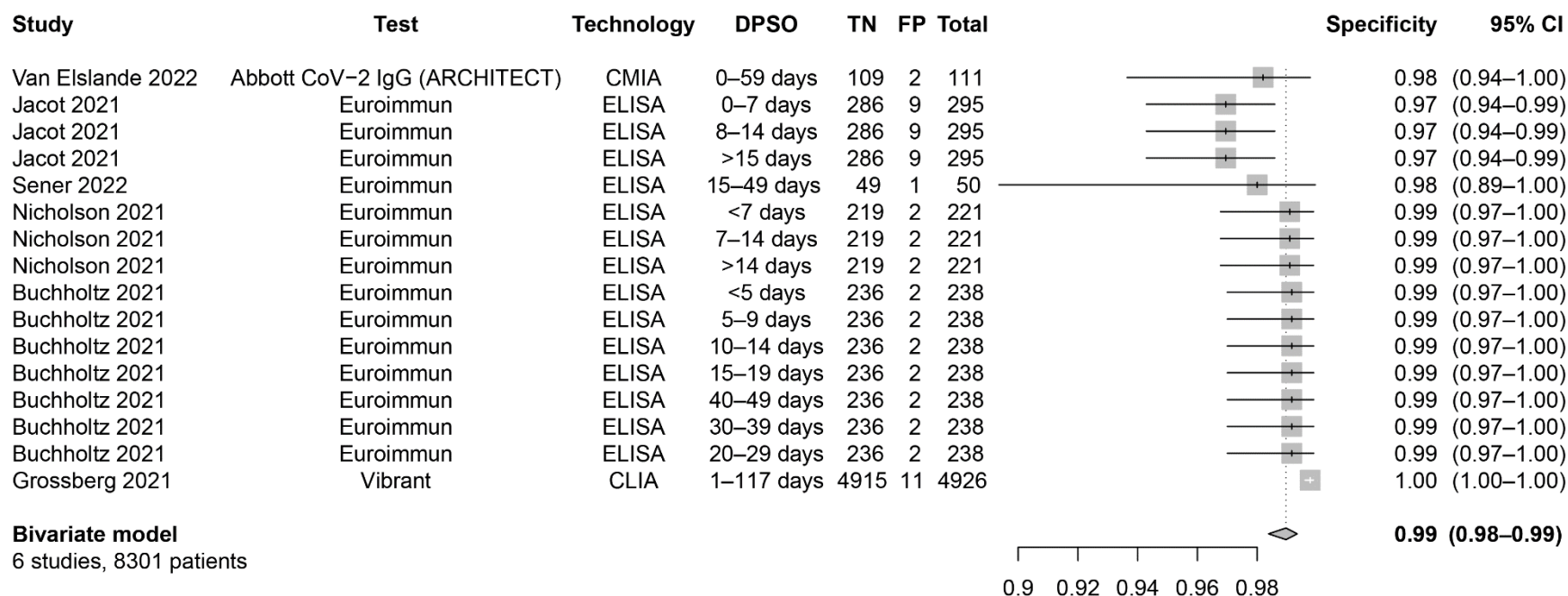


Figure s30b. Forest plot for the specificity of IgG assays targeting Nucleocapsid using NAAT as reference standard



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